No. GV002327

THE STATE OF TEXAS *ex rel.* VEN-A-CARE OF THE FLORIDA KEYS, INC. *Plaintiffs,* v. DEY, INC., ROXANE LABORATORIES, INC., WARRICK PHARMACEUTICALS CORPORATION, SCHERING-PLOUGH CORPORATION, and SCHERING CORPORATION *Defendants.*	§ § § § § § § § § § § § § § § § §	IN THE DISTRICT COURT OF TRAVIS COUNTY, TEXAS 53rd JUDICIAL DISTRICT

STATE OF TEXAS' NOTICE OF INTENTION TO TAKE ORAL DEPOSITIONS

TO: **FIRST DATA BANK, INC.**, by and through its attorneys,
Ms. Nicole Wong
Perkins & Coie,
180 Townsend St., 3rd Floor
San Francisco, CA 94107-1909

Mr. David Donaldson
George & Donaldson L.L.P
114 West 7th Street, Suite 1100
Austin, TX 78701

EXHIBIT
14
Hamilton

Please take notice that, under the Texas Rules of Civil Procedure, specifically Rule 201.1, Rule 205, Rule 199.2(b)(1) and Rule 176 among others, the State of Texas, will take the oral depositions of the following witnesses on the dates listed below, at the location indicated:

1. Mr. Joseph L. Hirschmann
Tuesday, November 12, 2002, 9:00 a.m. to 5:00 p.m.
180 Townsend St., 3rd Floor
San Francisco, CA 94107-1909

Deposition to begin at the above date and time, and resuming, if not concluded on that day, at 9:00 a.m. on the succeeding day.

2. Pursuant to Texas Rule of Civil Procedure 199.2(b)(1), the First Data Bank, Inc. representative or representatives who possesses the most knowledge of; J.H.

(A). the First Data Bank products known as the NDDF, NDDF Plus, Price Probe, Medicare Coverage Information, BaseLine Price, and HCPCS Average Pricing Data (Please note that knowledge of any "modules" within particular "knowledge base(s)" listed is also sought.); and

(B). the meaning, use, history, creation, and purpose of the following terms;
Average Wholesale Price ("AWP"),
Suggested Wholesale Price ("SWP"),
Wholesale Net ("WHLNT"),
"wholesale net price",
"direct price",
"baseline price",
J.H. — BaseLine Price ("BLP"),
"Medicaid AWP",
Average Generic Price,
Average Generic Pricing,
Federal Upper Limit,
Maximum Allowable Cost,
wholesale price,
Wholesale Acquisition Cost ("WAC"),
Average Manufacturer Price ("AMP"),
dead net price,
net price, or
wholesale cost,

and

(C). the generic pharmaceuticals industry, specifically the market pricing of generic pharmaceuticals, the sales of generic pharmaceuticals, and the reimbursement of generic pharmaceuticals.

Wednesday, November 13, 2002, 9:00 a.m. to 5:00 p.m.
180 Townsend St., 3rd Floor
San Francisco, CA 94107-1909

Deposition to begin upon the completion of the previous deposition.

The depositions shall continue from day to day until completed. The depositions will be recorded stenographically and on video tape. The stenographic recording will be conducted by Fredericks-Carroll Reporting & Litigation Services, Inc., 7719 Wood Hollow Drive, Suite 156, Austin, Texas 78731.

Respectfully submitted,

JOHN CORNYN
Attorney General of Texas

HOWARD G. BALDWIN, JR.
First Assistant Attorney General

JEFFREY S. BOYD
Deputy Attorney General for Litigation

LOWELL A. KEIG
Assistant Attorney General
Chief, Elder Law and Public Health Division

C. JARRETT ANDERSON
Assistant Attorney General
Office of the Attorney General
Elder Law and Public Health Division
State Bar No. 00796124
P. O. Box 12548
Austin, Texas 78711-2548
(512) 475-4097
(5120 499-0712 [Fax]

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **State of Texas' Notice of Intention to Take Oral Depositions** was sent via facsimile on this the 24th day of September, 2002, to the following:

Mr. Steven A. Fleckman
Ms. Julia Kenner
Fleckman & McGlynn
515 Congress Avenue, Suite 1800
Austin, Texas 78701
COUNSEL FOR DEY, INC.
FACSIMILE # (512) 476-7644

Mr. Steve McConnico
Mr. Eric Hagenswold
Scott, Douglas & McConnico, LLP
600 Congress Avenue, 15th Floor
Austin, Texas 78701-2589
COUNSEL FOR ROXANE LABORATORIES, INC.
FACSIMILE # (512) 474-0731

Mr. Stephen Hudspeth
Coudert Brothers
1114 Avenue of the Americas
New York, New York 10036-7703
COUNSEL FOR DEY, INC.
FACSIMILE # (212) 626-4120

Mr. C. Michael Moore
Locke, Liddell & Sapp, LLP
2200 Ross Avenue, Suite 2200
Dallas, Texas 75201-8001
COUNSEL FOR WARRICK PHARMACEUTICALS CORPORATION, SCHERING-PLOUGH CORPORATION and SCHERING CORPORATION
FACSIMILE # (214) 740-8800

Mr. James Breen
The Breen Law Firm
8201 Peters Road, Suite 1000
Plantation, Florida 33324
COUNSEL FOR RELATOR
FACSIMILE # (954) 499-1173

Hon. John E. Clark
Goode Casseb Jones Ricklin Choate & Watson
2122 N. Main Ave.
P.O. Box 120480
San Antonio, Texas 78212-9680
COUNSEL FOR RELATOR
FACSIMILE # (210) 733-0330

Ms. Susan S. Thomas
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103
COUNSEL FOR RELATOR
FACSIMILE # (215) 875-4636

Ms. Nicole Wong
Perkins & Coie
180 Townsend Street, 3rd Floor
San Francisco, CA 94107 -1909
COUNSEL FOR FIRST DATA BANK, INC.
FACSIMILE # (415) 344-7214

Mr. David Donaldson
George & Donaldson L.L.P.
114 West 7th Street, Suite 1100
Austin, Texas 78701
COUNSEL FOR FIRST DATA BANK, INC.
FACSIMILE # (512) 499-0094

C. JARRETT ANDERSON

** TX STATUS REPORT ** AS OF SEP 24 2002 16:49 PAGE.01

OFFICE OF ATT.GENERAL

	DATE	TIME	TO/FROM	MODE	MIN/SEC	PGS	JOB#	STATUS
28	09/24	16:44	512+499+0094	EC—S	02'06"	008	145	OK
29	09/24	16:47	Perkins Coie LLP	EC--S	02'11"	008	146	OK

OFFICE OF THE ATTORNEY GENERAL

FACSIMILE COVER SHEET

CONFIDENTIALITY NOTICE

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To: David Donaldson
499-0094

Nicole Wong
(415) 344-7214

From: Jarrett Anderson

Company: Elder Law & Public Health Division

Phone: (512) 475-4097

Fax: (512) 499-0712

Date: September 24, 2002

Pages (including cover page): 8

Comments: **Attached is a letter regarding discovery and the State of Texas' Notice of Intention to Take Oral Depositions.**

** TX STATUS REPORT ** AS OF SEP 24 2002 16:55 PAGE.01

OFFICE OF ATT.GENERAL

	DATE	TIME	TO/FROM	MODE	MIN/SEC	PGS	JOB#	STATUS
30	09/24	16:50	512 476 7644	EC--S	01'21"	005	148	OK
31	09/24	16:52	212+626+4120	EC--S	01'17"	005	148	OK
32	09/24	16:53	4740731	UF--S	01'10"	005	148	OK

OFFICE OF THE ATTORNEY GENERAL

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To: Mr. Steven Fleckman (512) 476-7644

Mr. Stephen M. Hudspeth (212) 626-4120

Mr. Steve McConnico & Mr. Eric Hagenswold (512) 474-0731

Mr. C. Michael Moore (214) 740-8800

Mr. James J. Breen (954) 499-1173

Hon. John E. Clark (210) 733-0330

Ms. Susan Thomas (215) 875-4636

From: Jarrett Anderson

Division: Elder Law & Public Health Division

Phone: (512) 475-4097

Fax: (512) 499-0712

Date: September 24, 2002

Pages (including cover page): 5

Comments: Attached is the State of Texas' Notice of Intention to Take Oral Depositions of First Data Bank representatives.

** TX STATUS REPORT ** AS OF SEP 24 2002 17:25 PAGE.01

OFFICE OF ATT.GENERAL

	DATE	TIME	TO/FROM	MODE	MIN/SEC	PGS	JOB#	STATUS
01	09/24	16:56	9544991173	EC--S	01'18"	005	148	OK
02	09/24	16:58	210 733 0330	EC--S	01'20"	005	148	OK
03	09/24	17:00	215 875 4636	EC--S	01'18"	005	148	OK
11	09/24	17:24 Locke Liddell		EC--S	01'45"	005	148	OK

OFFICE OF THE ATTORNEY GENERAL

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Ms. Susan Thomas (215) 875-4636

From: Jarrett Anderson

Division: Elder Law & Public Health Division

Phone: (512) 475-4097

Fax: (512) 499-0712

Date: September 24, 2002

Pages (including cover page): 5

Comments: Attached is the State of Texas' Notice of Intention to Take Oral Depositions of First Data Bank representatives.

OFFICE OF THE ATTORNEY GENERAL

FACSIMILE COVER SHEET

CONFIDENTIALITY NOTICE

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To: Mr. Steven Fleckman (512) 476-7644

Mr. Stephen M. Hudspeth (212) 626-4120

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Mr. James J. Breen (954) 499-1173

Hon. John E. Clark (210) 733-0330

Ms. Susan Thomas (215) 875-4636

From: **Jarrett Anderson**

Division: Elder Law & Public Health Division

Phone: (512) 475-4097

Fax: (512) 499-0712

Date: September 24, 2002

Pages (including cover page): 5

Comments: Attached is the State of Texas' Notice of Intention to Take Oral Depositions of First Data Bank representatives.

NAME: BaseLine Price™ and Date

MNEMONIC: BLP

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: 9(06), Price: 9(04)v9(05)

FIELD CONTENT:

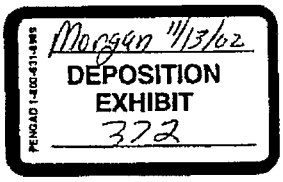
This is the BaseLine Price™ and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to a maximum of twenty-four segments.

NOTE: It is valid to have an effective date with a zero price. This would indicate a period when the BLP did not apply.

For additional information on the BLP™ please see Appendix Q.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to eight times depending on the user's requirements.



NAME:	Blue Book Average Wholesale Unit Price and Date
MNEMONIC:	BB
MESSAGE NUMBER:	320000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: 9(06), Price: 9(04)v9(05)

FIELD CONTENT:

This is the BB AWP unit price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to a maximum of eight segments, based on actual survey of drug wholesalers.

For additional information on the AWP please see Appendix G.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to eight times depending on the user's requirements.

NAME:	Blue Book Average Wholesale Package Price and Date
MNEMONIC:	BBPKG
MESSAGE NUMBER:	322000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: 9(06), Price: 9(04)v9(05)

FIELD CONTENT:

This is the BB AWP package price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to a maximum of three segments. Based on actual survey of drug wholesalers.

For additional information, please see Appendix G.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to three times depending on the user's requirements.

NAME:	Calculated Average Wholesale Package Price and Date
MNEMONIC:	CWPPKG
MESSAGE NUMBER:	312000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: 9(06), Price: 9(04)v9(05)

FIELD CONTENT:

This is the Calculated "AWP" package price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to a maximum of three segments.

For additional information, please see Appendix G.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to three times depending on the user's requirements.

NAME:	Calculated Average Wholesale Unit Price and Date
MNEMONIC:	CWP
MESSAGE NUMBER:	310000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date - 9(06), Price - 9(04)v9(05)

FIELD CONTENT:

This is the Calculated "AWP" unit price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to a maximum of eight segments.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to eight times depending on the user's requirements.

NAME:	Direct Unit Price and Date
MNEMONIC:	DIR
MESSAGE NUMBER:	340000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date - 9(06), Price - 9(04)v9(05)

FIELD CONTENT:

This is the manufacturer's Direct Unit Price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to a maximum of eight segments. Note that not all manufacturers sell direct, so not every record will have a direct price.

NOTE: It is valid to have an effective date with a zero price. This would indicate a period when the DIR did not apply.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to eight times depending on the user's requirements.

NAME:	Direct Package Price and Date
MNEMONIC:	DIRPKG
MESSAGE NUMBER:	342000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: 9(06), Price: 9(04)v9(05)

FIELD CONTENT:

This is the manufacturer's Direct Package Price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to maximum of three segments. Note that not all manufacturers sell direct, so not every record will have a direct price.

NOTE: It is valid to have an effective date with a zero price. This would indicate a period when the DIRPKG did not apply.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to three times depending on the user's requirements.

NAME:	MAC Unit Price and Date
MNEMONIC:	MAC
MESSAGE NUMBER:	360000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: 9(06), Price: 9(04)v9(05)

FIELD CONTENT:

This is the unit price for a drug under Federal MAC regulation and associated date. A drug record may contain one or more of these price segments, with the first one being the most current up to a maximum of six segments. Note that the Federal MAC program was replaced by HCFA with the "Federal Participation's Plan Upper Limits" on October 29, 1987. The MAC prices continue to apply, however, for drug claims with dates of service prior to October 29, 1987. The upper limits data element is described in Federal Participation's Plan Upper Limits (FFPUL; 999360).

NOTE: It is valid to have an effective date with a zero price. This would indicate a period when the MAC did not apply.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to six times depending on the user's requirements.

NAME:	Federal Participation's Plan Upper Limits
MNEMONIC:	FFPUL
MESSAGE NUMBER:	999360

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date - 9(06), Price - 9(04)v9(05)

FIELD CONTENT:

This is the "Big MAC" unit price and associated date for a drug published by HCFA in the State Medicaid Manual, revised August 1987, Section 6305, Upper Limits for Multiple Source and Other Drugs and revisions.

A drug record may contain one or more of these price segments, with the first one being the most current, up to a maximum of nine segements.

NOTE: It is valid to have an effective date with a zero price. This would indicate a period when the FFPUL did not apply.

If the user requires the old Federal MAC (MAC; 36000), First DataBank can merge the "Big MAC" and old Federal MAC into one price field.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary (4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to nine times depending on the user's requirements.

NAME:	Wholesale Unit Price and Date
MNEMONIC:	WHN
MESSAGE NUMBER:	390000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: s9(06), Price: s9(04)v9(05)

FIELD CONTENT:

This element provides a manufacturer's wholesale net unit price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current, up to a maximum of three segments. Note that not all manufacturers sell through wholesalers, so not every record will have a wholesale net price.

Note: It is valid to have an effective date with a zero price. This would indicate a period when the WHN did not apply.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary(4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to three times, depending on user's requirements.

NAME:	Wholesale Package Price and Date
MNEMONIC:	WHNPKG
MESSAGE NUMBER:	392000

FIELD SPECIFICATIONS:

Two numeric fields
Date in form YYMMDD and unit price
Picture: Date: s9(06), Price: s9(04)v9(05)

FIELD CONTENT:

This element provides a manufacturer's wholesale net package price and associated date. A drug record may contain one or more of these price segments, with the first one being the most current, up to a maximum of three segments. Note that not all manufacturers sell through wholesalers, so not every record will have a wholesale net price.

Note: It is valid to have an effective date with a zero price. This would indicate a period when the WHN did not apply.

USER EDITS:

The user may request the date as packed decimal (4 bytes) or zoned decimal (6 bytes). The price may be formatted in full word fixed binary(4 bytes), packed decimal (5 bytes) or zoned decimal (9 bytes). The date and price may occur up to three times, depending on user's requirements.

Telefax

Boehringer Ingelheim
Roxane Laboratories

Ms. Terri Factora
First DataBank
(650) 827-4578

Roxane Laboratories, Inc.

Page: 1 of 11

May 9, 2001

Karen Strelau
Telephone (440) 235-0272
Telefax (440) 235-2450
E-Mail kstrelau@cle.boehringer-ingelheim.com

P.O. Box 16532
Columbus, Ohio 43216-6532
Telephone (614) 276-4000

Dear Ms. Factora:

Roxane Laboratories, Inc. is pleased to announce the introduction of Albuterol Sulfate Inhalation Solution 0.083%, sterile unit dose vials packaged in color-coded, tamper-evident, ProtectPak™ foil packages. The product is available for immediate shipment in cartons of 25, 30 and 60 vials.

ALBUTEROL SULFATE INHALATION SOLUTION
0.083% (2.5mg/3mL)
Cartons of 25, 30 and 60 unit dose vials

NDC List 0054-	Strength	Package Size	Wholesale Cost	AWP
8063-11	2.5mg/3mL	3mL x 25 Unit Dose Vials	$5.85	$30.90
8063-13	2.5mg/3mL	3mL x 30 Unit Dose Vials	$7.00	$37.08
8063-21	2.5mg/3mL	3mL x 25 Unit Dose Vials	$13.80	$74.16

Also, attached please find the Package Insert and FDA Approval Letter.

Thank you in advance for adding this product to your prescription drug database.

Sincerely,

Karen L Strelau

Karen Strelau
Group Manager, National Accounts

Attachments

Morgan 11/3/02
DEPOSITION EXHIBIT
373

GH000110
TX-FDB02447

DEY, L.P.
2751 Napa Valley Corporate Drive
Napa, CA 94558
TEL (707) 224-3200 FAX (707) 224-8918

NEW PRODUCT ANNOUNCEMENT

October 2001

Attention: Pricing Database Administrator

Dey is pleased to introduce **AccuNeb™** (albuterol sulfate) Inhalation Solution. AccuNeb™ is indicated for the relief of bronchospasm in patients 2 to 12 years of age with asthma (reversible obstructive airway disease).

Following is a detailed description and pricing information for **AccuNeb™**.

Product	NDC#	Units/ Carton	WAC $	AWP $
AccuNeb™ (albuterol sulfate) Inhalation Solution 1.25 mg* / 3 mL	49502-0693-03	25	$32.00	$40.00
AccuNeb™ (albuterol sulfate) Inhalation Solution 0.63 mg* / 3 mL	49502-0692-03	25	$32.00	$40.00

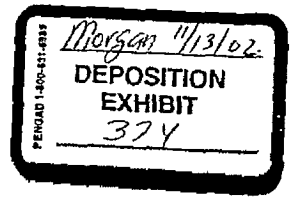
* Potency expressed as albuterol, equivalent to 1.5 mg and 0.75 mg albuterol sulfate.

As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees and other cost adjustments, which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of the invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid. As you know, the AWP listed here does not represent the actual price, which will be or has been charged or paid for this product. Generally, it is Dey's practice to set an AWP before a product is first sold and not to subsequently change that AWP. We understand that this is consistent with industry practice. We believe this to be clearly understood by state and federal Medicaid regulators.

We will begin shipping AccuNeb™ in October 2001. Product information has been enclosed for your records. Please update your database and fax a copy of the updated information to the attention of Virginia Farrat, Contract Analyst at 1-707-224-0988. Should you require further information, please feel free to contact Ms. Farrat at 1-800-755-5560 ext. 4110.

Sincerely,

Russell R. Johnston
Manager, Sales/Marketing Services



Attachments:
FDA Letter
Product Information Sheet
WAC Price List
AWP Price List

D9-373-01

DEY, L.P.
2751 Napa Valley Corporate Drive
Napa, CA 94558
TEL (707) 224-3200 FAX (707) 224-0988

NOTICE OF PRICE CHANGE

September 2002

Attention: Pricing Database Administrator

Please accept this letter as formal notification of the price changes noted below.

Effective November 1, 2002, Dey is increasing the Wholesale Acquisition Cost (WAC) pricing on the following products:

Dey WAC Price Increases... Effective November 1, 2002				
Product	NDC#	Carton Size	Old WAC $	New WAC $
EpiPen® Epinephrine Auto-Injector, 0.3 mg	49502-0500-01	1	39.90	41.90
EpiPen® Jr Epinephrine Auto-Injector, 0.15 mg	49502-0501-01	1	39.90	41.90
EpiPen® 2-Pak® Epinephrine Auto-Injector, 0.3 mg	49502-0500-02	2	77.90	80.25
EpiPen® Jr 2-Pak® Epinephrine Auto-Injector, 0.15 mg	49502-0501-02	2	77.90	80.25

Effective November 1, 2002, Dey is increasing the Average Wholesale Price (AWP) on the following products:

Dey AWP Price Increases... Effective November 1, 2002				
Product	NDC#	Carton Size	Old AWP $	New AWP $
EpiPen® Epinephrine Auto-Injector, 0.3 mg	49502-0500-01	1	47.88	50.27
EpiPen® Jr Epinephrine Auto-Injector, 0.15 mg	49502-0501-01	1	47.88	50.27
EpiPen® 2-Pak® Epinephrine Auto-Injector, 0.3 mg	49502-0500-02	2	94.00	96.82
EpiPen® Jr 2-Pak® Epinephrine Auto-Injector, 0.15 mg	49502-0501-02	2	94.00	96.82

As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees and other cost adjustments, which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of the invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which are being reimbursed under Medicaid. As you also know, the AWP listed here does not represent the actual price, which will be or has been charged or paid for this product. Dey believes this to be clearly understood by state and federal Medicaid regulators.

GH000112

E9-328-01

7-15-01

PriceAlert

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Volume 13; Number 7

PriceAlert is published monthly for $129.00 per year by First DataBank, 1111 Bayhill Drive, San Bruno, CA 94066.

POSTMASTER: Send address changes to
First DataBank PriceAlert
P.O. BOX 40930
Indianapolis, IN 46240
For additional information, please call 1-800-388-8884

A Publication of
First DataBank Inc.
The Hearst Corporation

Frank A. Bennack, Jr., President
George R. Hearst, Jr., Chairman
Victor F. Ganzi, Executive Vice President
Richard P. Malloch, Vice President and Group Head
Joseph L. Hirschmann, President, First DataBank Inc.

To Complain is Human, To Praise is Divine

I have used poetic license with the phrase, "To err is human, to forgive, Divine." It seems that for as long as I have been in pharmacy, that people have complained about the high price of pharmaceuticals. The high price of pharmaceuticals has been credited as the cause of many problems. It seems that the arguments always heat up around National elections. I have come to accept that people will complain about the price of pharmaceuticals no matter what. Paying for pharmaceuticals seems to fall in the same category as car repairs or plumbers. No one wants to pay for them, so they are always too high. Albeit, all of these are necessary and perhaps we complain because we would just as soon not be confronted with the situation. Are we really complaining about the situation or are we complaining about the price as a substitute for the situation (did not take care of myself, car or plumbing like I should).

Now, we have had some manufacturers actually lower their prices. Some of these reductions were quite dramatic. This resulted in a lowering of AWP pricing for these products. One would have logically thought that these manufacturers would have received praise for taking such an action. Unfortunately, this did not happen. In fact, it seems that the complaints are even louder over lowering prices than over raising prices. Instead of receiving praise for lowering prices, I have heard much speculation regarding negative reasons for why the prices were lowered. Such behavior would seem to say, raise your prices because no matter what you do you will receive complaints, so why not make more money with higher prices. Yes, I am familiar with contract pricing, spread, profit margins and all those terms. Additionally, I am all for making money. However, the world of pharmacy (and I mean everyone involved with pharmacy) needs to work together for the promotion of pharmaceuticals instead of always complaining about the actions of each other. Such behavior leaves the public thinking we are all unscrupulous and/or just always complaining. When someone does something that pharmacy has been requesting, let us praise the action instead of complaining even more about the situation.

Let us remember that we are all here to make patients' lives better and work toward that goal. Let's hear more praise and less complaining.

Kay Morgan

PriceAlert contains pricing information on over 1700 items and approximately 13,000 NDCs. It is an edited list of leading Rx and OTC products. Injectables and unit dose items are only included if commonly seen in retail pharmacy.

Contents

3-15-2000

PriceAlert

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Average Wholesale Price

I have had many conversations regarding what "AWP" is and how FDB determines it. There is much folklore and misunderstanding as to the determination of AWP and how we obtain the data.

AWP is the average **wholesale** price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product(NDC),often referred to by FDB as the "Blue Book Price". The operative word is ***average***. AWP was developed to provide a price, which all parties could agree upon.

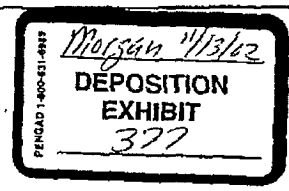
In order to determine the AWP, First DataBank surveys national wholesalers to ascertain what the price is. This is based on their AWP price files. We contact the wholesalers to determine what the markup should be for a new company. First DataBank then confirms that the markup is accurate and current. A survey may be performed on a single NDC number or on a manufacturer's entire product line. In either case, a survey will be performed with all national wholesalers to determine the appropriate AWP.

With increased numbers of surveys done, the determination represents over two-thirds of the volume of the wholesalers, and is also representative of wholesalers on a national level. Because individual wholesalers may mark up each manufacturer differently, a weighted average, not a consensus average, is calculated. That is, the market share held by the wholesalers surveyed affects the markup factor proportionally. Therefore, wholesalers with higher drug dollar volumes have more weight in the determination of the final markup. Thus, a higher degree of certainty is achieved. We also consider the manufacturer's suggested wholesale price (SWP) in our determination.

Many customers are under the impression that the manufacturer sets the AWP. This is not true. FDB reports the wholesale price suggested by the manufacturer as "Suggested Wholesale Price (SWP)". The SWP is a different data element on the NDDF file for those customers who want to use SWP instead of AWP. Frequently, the SWP and AWP are the same. However, we are having more instances where they are different. We will populate the SWP with the new mark-up, but will survey the national wholesalers to determine AWP. The AWP will be populated with the wholesaler survey price even if it disagrees with the SWP.

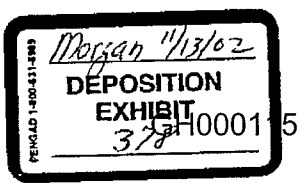
In most cases, the results from surveys match what First DataBank is using. In the instances that they do not, it is First Databank's policy to change the markup to report marketplace reality.

Kay Morgan



Contents

1. WHOLESALE COST
2. WHOLESALER COST
3. PRICE TO WHOLESALER
4. WHOLESALE ACQUISITION COST
5. WHOLESALE NET
6. WHOLESALER NET COST
7. WHOLESALE PRICE
8. WHOLESALE ACQUISITION PRICE



DEY LABORATORIES
2751 Napa Valley Corporate Drive
Napa, CA 94558
TEL (707) 224-3200 FAX (707) 224-8918

Fax to: Eve Gmeiner
Company: Dey Laboratories
Fax number: 707-224-0495
Total # of pages: _____

PRICING DATABASE CONFIRMATION FORM

This confirms that I have made the changes in our database concerning AWP / WAC (circle all which apply) pricing for the following Dey product which is now effective:

PRODUCT	NDC NUMBER
Ipratropium Bromide Inhalation Solution 230-vial pack	49502-685-33

Company Name: First DataBank

Name of person filling out this form: Kathy Gautagsell

Phone number: 415-872-4521

Fax number: 415-827-4578

These changes will appear in our system on the following date: 8-11-97

These changes will be available to our customers to update their pricing databases on the following date: 8-14-97 or 7-28-97

Please fill in this form and fax it, along with a *copy of the print screen of your company's database* (indicating the change has been made in your system), to Eve Gmeiner at the number listed at the top of the page. No cover sheet is necessary.

Thank you very much for your assistance. If you have any questions please contact Eve Gmeiner at 707-224-3200 x 744.

Morgan 11/13/02
DEPOSITION EXHIBIT
329

Page: 1 Document Name: Cics

08/12/97 F I R S T D A T A B A N K NDDF-D1
13:26:52 N D D F V I E W S C R E E N LINE 0

NDC	49502 - 0685 - 33	BN	IPRATROPIUM BROMIDE		GCN	42235	D
PNDC	- -	LN	IPRATROPIUM BR 0.02% SOLN		PS	2.	
REPNDC	- -	GNN	IPRATROPIUM BROMIDE		OBSDTE	000000	
AD	30'S,U-D,P/F	AHFS	120808	DACCES	970811	CL	F
CSP	0000030	GC3	A1D	DADD	970811	DEA	0
DOSE	SOLUTION	GTC	14	DESDTE	000000	DESI	
MFG	DEY LABS.	TC	15	DAWP	970811	GI	1
LBLRID	A49502	DCC	0	HOSP	1	GPI	1
RT	INHALATION	PD	BOTTLE	IPI	0	PPI	
STR	0.2MG/ML	TOP200	000	MINI	0	STPK	0
GC	A1DXJ2BV000000000000-BR00-50200-SAH			REPACK	0	UD	1
DLC				DAC	370000	USC	
IACOD0				DRC			
IACOD1				FOOD			
IVCOD1				LBL	1314000000		
IVCOD2				OBC	AN		
IVCOD3				PEC	522205		
IVCOD4				GCNSQN	021700		

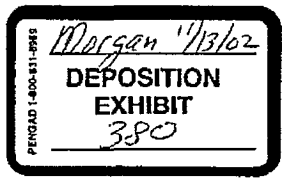
SKEY
TOP OF PAGE, PFKEY 7 WILL RETURN TO PAGE MODE
1 HLP 2 TPF 3 EXIT 4 CLN 5 PRC 6 MSC 7 PB 8 PF 9 PRC1 10 HCFA 11 D

te: 8/12/97 Time: 01:25:49 PM

Laboratories did change the WAC price for Albuterol 49502-0697-03 it
reased from 14.50 to 11.25 effective 8-1-97. That is the change the
olesaler is reporting to the customer. We've updated the price that changed,
ut we're okay on the AWP.

/var/opt/brock9.0.5/bcslocal/textfiles/resolutions/r_33728.txt 1/ 1

F1	F2	F3	F4	F5	F6	F7	F8
Next Page		Inter-fone	Exit		Print File	First Page	



01 barkerj Medi-Span Problem Ticket Profile - Page 1 bcslocal

Actions* N

Acct ID 243474 Company Eagle Managed Care

Contact Angela Franklin Ph# 800-545-5591 x 6753
Ticket # 38436 Status Opened
MS Prod* ALL Purchased N NDC 49502068912 GPI
Version Rsl # Drug Name CROMOLYN SOD NEB 20MG/2ML

49502 Dey

Tkt Priority* Normal Due Date 10/28/1997 Original Due Date 10/28/1997

2 L#1 Code/Description DATA INTEGRITY ISSUES
3 L#2 Code/Description DATA VERIFICATION
2 L#3 Code/Description PRICE

Customer
Objective Phcy being reimbursed/below his cost for this drug. Price hasn't changed since '94. Asked us to verify as current.

On-File Eff:
AWP = 84.00 5/1/94
WAC = 66.00 5/1/96

New Price: Eff:
AWP = 84.00 8/1/97
WAC = 54.30 8/1/97

Record 1 of 1.

F1	F2	F3	F4	F5	F6	F7	F8
Accept Info	Replcmnt Order	Resoln Summary	Save & Exit	Contacts	Schedule Callback	Second Page	Change F-Keys

DEPOSITION EXHIBIT 381 Morgan 11/13/02

I had Rec'd "WAC" Pricing from a fax on entire WAC/AWP price file was waiting on AWP - be processed then She Asked if I would = 2648E PC/PC Report under reqd. Sent on 10/29/97. Never Heard any more. I apologize for taking so long.

FDB 002357

TX-D & W - 012279

RECEIVED DEC 1 2 1997

RECVD
ENTRY E ____ QC ____
CODE C ____ QC ____
FILE ____ # TO CODE ____

MFTR Dey Labs
EFF DT 8/1/97
FMT ____ LAB 49502 DLAB ____
AWP ____ WAC ____ DP ____ DPPF ____
WAPF1 QTY ____ WAPF2 ____ WAPF ____

GH000119

F A X

TRANSMISSION

DEY LABORATORIES
2751 NAPA VALLEY CORPORATE DRIVE
NAPA, CA 94558
(800) 755-5560
FAX: (707) 224-0495

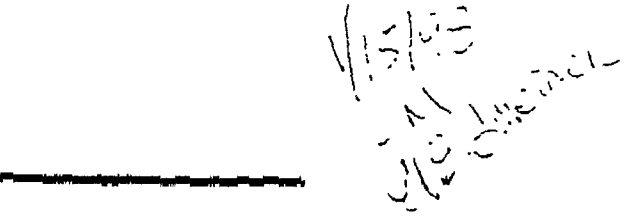
Date: December 31, 1997

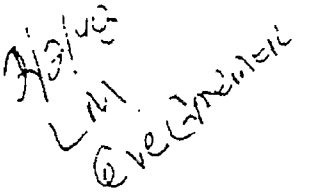
To: Connie Westbrook
MediSpan

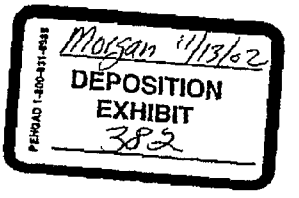
Fax #: 317-469-5252

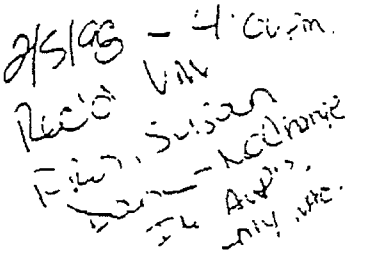
From: Eve Fagrell Gmeiner
Product Manager

Pages: 2 (including this one)









FDB 002368

RECEIVED JAN 0 2 1998

RECVD

ENTRY E CLI CLOSER QC NLA 2/9/98

CODE C QC

FILE NLA 2/9/98 # TO CODE

MFTR Dey Labs

EFF DT 1/1/98

FMT 12 LAB 49502 DLAB

AWP 9 WAC S DP N DPPF

WAFF1 WAFF2 WAFF3 20618

FTY SCEN 3 TYPE Part #

GH000120

TX-D & W - 012290

DEY LABORATORIES
2751 Napa Valley Corporate Drive
Napa, CA 94558
TEL (707) 224-3200 FAX (707) 224-8918

December 31, 1997

Ms. Connie Westbrook
Data Acquisition Specialist
Medispan
8425 Woodfield Crossing Blvd.
P.O. Box 40930
Indianapolis, IN 46240-0930

Dear Connie:

Effective January 1, 1998, Dey Laboratories is reducing our wholesale acquisition cost (WAC) pricing on the following products as listed below in the table.

NDC/ Order Number	Description	Size	Units / Ctn	Ctns / Case	OLD WAC ($)	NEW WAC ($)
49502-697-03	Albuterol Sulfate Inhalation 0.083%	3 mL	25	12	11.25	9.50
49502-697-33	Albuterol Sulfate Inhalation 0.083%	3 mL	30	12	13.50	11.40
49502-697-60	Albuterol Sulfate Inhalation 0.083%	3 mL	60	12	26.70	22.80
49502-689-02	Cromolyn Sodium Inhalation Solution USP	2 mL	60	6	27.75	23.75
49502-689-12	Cromolyn Sodium Inhalation Solution USP	2 mL	120	6	54.30	46.90
49502-685-03	Ipratropium Bromide Inhalation Solution	2.5 mL	25	12	25.50	20.25
49502-685-33	Ipratropium Bromide Inhalation Solution	2.5 mL	30	12	30.60	24.30
49502-685-60	Ipratropium Bromide Inhalation Solution	2.5 mL	60	12	60.90	48.60

Please update your database records to reflect these changes. If you have any questions, please contact me at (707) 224-3200 x745.

Eve Gmeiner
Product Manager

FDB 002369

Please see full prescribing information.
Proventil is a trademark of Schering Corporation.
Ventolin is a registered trademark of Allen & Hanburys, Division of Glaxo Wellcome, Inc.
* Potency expressed as albuterol

A Dey Laboratories Company

GH000121
TX-D & W - 012291

DEY LABORATORIES, INC.
2751 Napa Valley Corporate Drive
Napa California 94558
TEL (707) 224-3200 FAX (707) 224-3235

June 21, 1991

Edward Edelstein RPh.
First Databank
1111 Bayhill drive, Suite 350
San Bruno, CA. 94066

RE: UPDATED PRODUCT LISTING

Dear Ed,

Enclosed please find our updated AWP price list reflecting the three new products sold by Dey Laboratories.

As I mentioned to you in my letter dated January 4, 1991, all Dey Laboratory products will be marketed under their generic names with the exception of our Dey-Wash™, which should be listed under the brand name.

We would appreciate it if you could include these additions in your 1991/1992 Blue Book issue and the next Price Alert issue.

Many thanks for your cooperation.

Kind regards,

Helen Burnham

Helen Burnham
Marketing Manager

HB:ms

Enclosure

FDB 000932

TX-D & W - 012437

Morgan 11/13/02
DEPOSITION EXHIBIT
383

A Lipha Americas company
GH000122

DEY LABORATORIES, INC.
2751 NAPA VALLEY CORPORATE DRIVE
NAPA, CA 94558
TEL: (707) 224-3200
FAX: (707) 224-3235

DATE: 2/24/92

TO: Candy Ogden First Data Bank

FIRM: R.E.: Price Alert and Pharmacy Blue Book update

NO.: (415) 588-6867

FROM: Helen Burnham, Marketing Manager

Number of pages, including this one: 2

* * * * * * *

MESSAGE:

Attached please find our updated AWP and Direct Price list for Dey products.

Please note our new product: Albuterol Sulfate
Inhalation Solution 0.083%
3 mL Unit-Dose

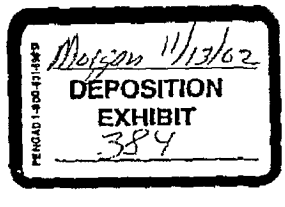
Kindly update your database to reflect the new changes.

If you have any questions, please contact me on 1-800-755-5560 ext. 234.

Regards,

Helen Burnham

FDB 000930



TX-D & W - 012435
GH000123

Actions* N

Acct ID 235950 Company American Drug Stores

Contact Reisa Wade Ph# 847-916-4384 x
Ticket # 49841 Status Opened
MS Prod* ALL Purchased N NDC 59930150008 GPI
Version Rsl # Drug Name ALBUTEROL NEB 0.083% QTY 60 Pk.sz. 3

Tkt Priority* Normal Due Date 04/07/1998 Original Due Date 04/07/1998

2 L#1 Code/Description DATA INTEGRITY ISSUES
2 L#2 Code/Description CUSTMR DISAGREES W/DATA
1 L#3 Code/Description PRICE

Customer
Objective FDB is outputting an AWP of $36+..we have an AWP of $30.25..can we verify?

Record 1 of 1.

F1	F2	F3	F4	F5	F6	F7	F8
Accept Info	Replcmnt Order	Resoln Summary	Save & Exit	Contacts	Schedule Callback	Second Page	Change F-Keys

Bea Jackson

(Currently)
(on system)
awp = $ 30.25 eff 10.12.93

Wallick Pharma / 59930

DATE/TIME OF ISSUE
DATE/TIME I.C. 4.6.98 / 8:21 am.
FOLLOW UP

RESOLUTION DATE 4.8.98 / 3:12 pm

verified with ~~Amy Shivett~~, our pricing is correct!

FDB 002229

DEPOSITION EXHIBIT 385 Morgan 11/13/02

TX-D & W 012321

GH000124

DEPOSITION SUMMARY
Patricia Kay Morgan
Taken 11/13/02
Pharmaceutical Qui Tam 22106

Page: line	Topic	Summary	Key Questions
6:4 to 10:8	Name, general admonitions	The deponent is Patricia Kay Morgan. She is a representative of First Data Bank.	
12:16 to 13:7	Document retention policy	To her knowledge, First Data Bank does not have a Document Retention Policy. In her department, they retain the pricing information the current year plus two years.	
13:23 to 14:3	Position	She is the manager of editorial services at First Data Bank. She has held that position since she joined First Data Bank in April 1999.	
14:16 to 15:5	Pricing terms	Average wholesale price does not have a standard definition. At First Data Bank they call it a bluebook price that is used by many of their customers to be the AWP. But First Data Bank's definition is the price charged by the wholesaler, the published price from the wholesaler to the retail customer.	
15:6 to 15:7	Retail customer	Retail customers are generally retail pharmacies.	
15:8 to 15:11	Who creates AWP	It is the wholesalers that assign the AWP.	
15:12 to 15:18	AWP not set by the manufacturer	According to the First Data Bank definition, AWP is not set by the manufacturers. They use the wholesaler.	
15:19 to 15:25	Suggested wholesale price	For the manufacturers that suggest AWPs, First Data Bank populates those into a field called Suggested Wholesale Price and then depending upon the survey if the wholesalers agree with that price, it would be published in the bluebook field.	

Page: line	Topic	Summary	Key Questions
17:2 to 17:7	Prompt a survey	A customer -- payers and providers -- saying that they think the markup should be different than what it is would prompt a survey.	
18:7 to 18:12	Wholesaler survey	When First Data Bank conducts a wholesaler survey, they conduct it for only one given manufacturer. They conduct less than two wholesaler surveys per manufacturer per year.	
18:23 to 19:5	What would prompt a survey	A merger, an acquisition, a divestiture would prompt a need to survey a wholesaler. Or it could be the change in the manufacturer's reporting of the data to First Data Bank.	
19:17 to 19:22	Manufacturers notify they've changed the way they report their prices	Generally First Data Bank receives notification of the manufacturers price changes and if it is different than what they received in the past, it is up to First Data Bank to figure it out.	
19:23 to 20:14	Receive pricing information	They receive pricing information from manufacturers by mail, by fax, by e-mail.	
21:4 to 21:7	Wholesaler surveys	The wholesaler surveys are a weighted average using market share.	
23:5 to 23:13	Market share	McKesson's market share is number 3, and they used to be number one. Amerisourcebergen has gone to two and Cardinal is number one.	
24:14 to 24:21	Did not disagree on markup percentage	The three wholesalers: McKesson, Amerisourcebergen and Cardinal have never disagreed regarding the markup percentage.	
25:25 to 27:5	AWP pricing information	The information is supplied to her by a manufacturer is the same as that which is supplied to a wholesaler.	Do you have information that the manufacturers who submit AWP pricing information at First Data Bank are submitting that same AWP pricing information to the three national wholesalers: McKesson, Amerisourcebergen

Page: line	Topic	Summary	Key Questions
			and Cardinal?
27:22 to 28:8	AWP pricing information	At First Data Bank, the manufacturers are submitting the same AWP pricing information to the full line national wholesalers: McKesson, Cardinal and Amerisourcebergen that they are submitting to First Data Bank.	
28:9 to 29:12	Bluebook markup does not agree with the AWPs that are submitted	Merck wanted to have a 20% markup versus a 25 on some other product line. The wholesaler did not go along with it and neither did First Data Bank. Merck was competing with a product that had a 20% markup and they had a 25% markup. But they wanted to lower their markup to their competitors. At the time the competitor was Searle (in 1999 or 2000). It concerned Celebrex and Vioxx.	
29:16 to 29:23	Reason for lowering their markup	They wanted to lower their markup (Merck) because they were competing with a product that had a different markup. No other explanation was given.	
30:9 to 30:11	Markup	When talking about markups, it is a markup over the wholesale acquisition cost.	
30:12 to 30:16	Bluebook	It is the field that is called Bluebook and is interpreted as AWP.	Once that markup is applied to the wholesale acquisition cost, that results in an AWP at First Data Bank?
31:13 to 32:2	Frequency of dosage	The frequency of dosage becomes important, not just the cost per tablet, when manufacturers are promoting their products to payers (of pharmaceuticals).	
32:3 to 32:13	Payer	"Payer" is usually described as managed care. She does not know if includes Medicaids or PBMS.	
34:10 to 35:9	Relationship with profit margins and	The markups had a relationship with the wholesaler profit margins.	

Page: line	Topic	Summary	Key Questions
	markups	She does not know what the relationship is or how they determine that. It is her understanding the markups are assigned by the wholesalers and those were assigned based on the wholesaler's profit margins relative to those products.	
35:10 to 35:12	Profit margins could change	The wholesaler's profit margins could change from manufacturer to manufacturer.	
36:14 to 37:6	Merger	Yes. Pfizer purchased Parke-Davis. First Data Bank surveyed the wholesalers to see what markup they were going to apply because Pfizer had been a 25% markup and Parke-Davis at a 20. So they determined that a 25% markup would be applied to al Pfizer products which were formerly Parke-Davis but now Pfizer.	Can you provide an example where a merger occurred and that prompted First Data Bank to conduct a wholesaler survey?
38:9 to 39:20	Protonix, manufactured by Wyeth	Wyeth wanted to have a different markup on one of their products -- protonix. The wholesalers did not want to go along with that. Wyeth is a direct selling company. They were at a 25% markup and wanted 20% on their protonix. The wholesalers accepted Wyeth's desire t lower the markup to 20% for about a year. Then it went back to 25%.	
40:2 to 40:11	"wholesale net"	"Wholesale net" is a name of their field for wholesale net pricing or wholesale acquisition cost.	
40:12 to 40:21	Wholesale net prices	First Data bank receives wholesale net prices from the manufacturer. It is defined as the published price from the manufacturer.	
44:8 to	Customers demanding	It is primarily the payer market, the people paying for the prescriptions that	

Page: line	Topic	Summary	Key Questions
44:15	that First Data bank publish wholesale net pricing	are demanding that First Data bank publish wholesale net pricing	
46:18 to 47:4	At a competitive disadvantage ?	She does not know of anyone being competitively disadvantaged because of information they have published or not published.	TO the extent that First Data Bank is able to obtain the wholesale net pricing from other sources and publish it, does that put those manufacturers at a competitive disadvantage?
47:5 to 48:3	Definition of wholesale net	First Data Bank defines "wholesale net" as the published price from the manufacturer to the wholesaler. She does not know when First Data Bank started using the Wholesale Net pricing term but it predated her employment with Firs Data Bank.	
48:4 to 48:16	Prior employment	She worked at Abbot Laboratories prior to her employment at First Data Bank. She was employed at Abbot Labs for 23 years. She communicated with First Data Bank through Abbot for about 10 years	
49:1 to 49:8	Submitted information to Medicaid	She was the person at Abbott that was responsible for submitting pricing information to Medicaid because she did the mailings. And as part of that, First Data Bank got a copy of that correspondence.	
49:9 to 49:22	Job responsibilities	She was involved with the states that had formularies and making presentations to those states to make sure the products were on the formulary. After Obra '90 it was more of a fact of notifying the states that they had introduced anew product or had added a new dosage form, a new package size.	What were your job responsibilities at Abbott in placing Abbott products on Medicaid formularies.
49:23 to	Significance	When Obra '90 was first passed, the	

Page: line	Topic	Summary	Key Questions
50:11	of Obra ,90	manufacturers were to pay rebates to the state based on the utilization of their products. In exchange for those rebates all products were to be reimbursed by the state at that point in time. That has changed. Now states may place products on prior authorizations and not just have what's called open formularies where they pay for everything.	
50:23 to 51:6	Pricing information	After the implementation of Obra '99, she submitted pricing information on behalf of Abbot Labs to Medicaid. She submitted information on new products, including clinical information. She did not submit ongoing pricing updates to the state medicaid or First Data Bank.	
51:7 to 51:10	Pricing department	They had a pricing department at Abbott that was responsible for submitting updated pricing to the state medicaids.	
51:11 to 51:15	Pricing for new products	They would submit their list price and wholesale acquisition cost for new products being added to State Medicaid formularies.	
51:16 to 52:1	AWP*	Abbot would submit one (AWP) that was suggested. It was always with and asterisk. It would say AWP*. It meant that the company did not set AWP but that was what they had calculated it to be based on historical AWP.	
52:14 to 53:12	Synonyms	The term "wholesale net" was not used at the time she was at Abbott. They actually called it wholesale price and list price. Wholesale price is a synonym for wholesale acquisition cost.	Did you understand that WAC and Wholesale Net were synonyms when you were at Abbott?

Page: line	Topic	Summary	Key Questions
		And wholesale price is a synonym for wholesale net.	
54:2 to 54:10	Discounts	She is aware of volume discounts and early payment terms.	
54:11 to 54:20	Rebates	Rebates do lower prices. She is aware of Medicaid rebates.	
55:4 to 55:17	Chargeback	Her understanding of a chargeback is where the manufacturer has a contract with a customer such as a hospital for a certain price on a product. The hospital is buying it from a wholesaler, but the manufacturer had sold it to the wholesaler at a higher price. SO the wholesaler in turn sells it o the hospital at the price that the contract between the manufacturer and the hospital says it will be sold at and the wholesaler charges back to the manufacturer the difference between what they paid and the contract price to the hospital.	
57:5 to 57:24	Methods of classifying a drug as a brand or a generic	1. Generic indicator: is the product available from a single source or more than one source? 2. Generic name indicator: does this product have a generic name or does it have a name that does not equal the generic name of the product? 3. Generic manufacturer indicator: which manufacturer is specified? Is the manufacturer a brand manufacturer or generic manufacturer? 4. Generic therapeutic indicator: does the product have an orange book rating of equivalence or not equivalence? 5. Generic spread indicator: indicates what the spread is between the wholesale acquisition price and the AWP if known. 6. Generic price indicator: compares the price of that product to the other products in the category and says what	

Page: line	Topic	Summary	Key Questions
		it thinks the price of the product is.	
57:25 to 58:13	Used in determining whether they will reimburse a product as brand or generic	They have upper limits that they apply to products that are available from multi-sources. It is not a matter of whether it is a brand or a generic. It is how much you are going to get paid.	Which of the classifications that First Data Bank uses to classify Brands or Generics is utilized by Medicaids in determining whether they will reimburse a product as a brand or generic?
58:14 to 58:22	Classify products and brand or generic	First Data Bank classifies products as brand or generic because their customers have requested that First Data bank help make determinations on them.	
58:24 to 59:14	10% rule	She has not heard of the '10% Rule' and First Data Bank has not used a 10% rule.	
61:13 to 61:23	Generic Spread Indicator	First Data Bank has a field called Generic Spread Indicator.	
62:15 to 63:9	Use of "spread"	Use of the term 'spread' has to do with how you do the math. A 20% markup = a 16 2/3 spread. A 25% markup = a 20% spread. She has only heard of the use of the work "Spread" as it relates to the difference between the wholesale acquisition cost and the AWP.	
67:11 to 68:2	Maximum allowable cost	She is not familiar with maximum allowable cost as it is not really a First Data Bank term. But back in the '80's the Federal Government was setting maximum allowable cost on some multi-source drugs. They ceased that practice in the late 80" and that is all she knows about it.	
68:3 to 68:24	Federal upper limits	Federal Upper Limits is a term that CMS uses, formerly known as HCFA, for the amount they consider to be their reimbursement level or multi-source	

Page: line	Topic	Summary	Key Questions
		drugs. It is neither. It is a guidance to the states.	
69:7 to 69:16	How federal upper limit is calculated	According to the regulations, federal upper limit is 150% of the lowest price generic.	
69:17 to 71:0	Pharmaceutical equivalent	The prices have to be listed in the Orange Book using the Orange book criteria which would subsequently go to a therapeutic equivalent.	
		Examination by Mr. Breen:	
75:5 to 75:22	Direct price	She recalls first having heard the term 'direct price' n the 80's when she was working for Abbott. Abbott sold direct, so they had a direct price.	
77:5 to 77:8	Publish	First Data Bank publishes electronic media.	
77:9 to 77:14	Reporting business	First Data Bank is in the reporting business. They report information.	
77:15 to 77:23	Manufacturer	Abbot is in the business of selling prescription pharmaceuticals. They are a manufacturer.	
80:13 to 80:24	Consistent with FDA regulations	First Data Bank reports information on drugs that is consistent with FDA requirements so that it can be useful to whoever buys their information.	
81:14 to 81:19	Policies	First Data Bank has editorial policies that enable it to determine what information it will report that it gathers from sources like Abbot.	
82:10 to 82:19	Direct price	The term 'direct price' means the same thing at First Data bank that it meant when she was at Abbott. It is the published price from the manufacturer to non-wholesalers.	
83:17 to 84:	Direct price information	On receiving information, from First Data Bank's perspective, it is the correct information that the company intends to report. Direct price is the published price.	
85:18 to	Correct price	Yes.	If you get a correct price from

Page: line	Topic	Summary	Key Questions
86:3		It is an assumption that there is no reason to do more than just accept it and report it.	Roxane about their drugs, is it First Data Bank's role to make sure that's the price that Roxane intends to be reported before you report it?
89:1 to 89:17	Credible	First Data Bank receives information from manufacturers stating what their direct price is, their wholesale price is. They have no reason to doubt that it is not credible.	
91:15 to 97:25	Exhibit 368	This is a report about WAC histories. It is possible that this report may have been the result of a Medi-Span database and not the First Data Bank database. But during the time frame that Medi-Span was owned by First Data Bank, they had separate databases.	
100:13 to 101:20	Need to be on letterhead	Getting a letter from Roxane, from a major warehouse -- wholesaler like McKesson stating what their wholesale nets were or their WACS were, First Data Bank would believe that was a sufficiently reliable source to then report the WAC pricing to Roxane. It has to be on letterhead. That helps verify the authenticity of the information.	
102:4 to 102:18	Confirm authenticity	The Wholesale Net comes from the manufacturer's published price to wholesalers.	
103:9 to 104:1	Customized file	She makes the information available to be reported to First Data's customers. She has prescribed criteria that she used to put the data on there. It is then up to the customers. They receive a customized file from First Data Bank. They get what they have requested to receive from First Data Bank.	
104:3 to 104:10	What she puts in, is not	The data is used to be reported to customers in whatever format the customer has agreed with first Data	

Page: line	Topic	Summary	Key Questions
	necessarily what they get	Bank. But they may have formulas applied to the pricing fields that change those pricing fields when they receive it.	
104:22 to 105:4	Possible changes	It is possible that a company like Dey, Warrick, Roxane or Abbot reported a direct price and that was changed by a formula or algorithm before it got reported to a State Medicaid program.	
105:5 to106:5	Get direct pricing	If the state did not have an algorithm that would change the direct price that went into the system, then the direct price that would come out of the system and get reported to the sate would be the same as what the manufacturer reported to First Data bank.	
106:21 to 106:25	Pricing surveys	First Data bank conducts pricing surveys to determine the markup to be applied to a manufacturer or a specific NDS generally.	
107:13 to 107:23	Bluebook AWP	First Data bank does the surveys to verify the markup proportions that they are applying. And they do that so they can determine what bluebook AWP to use to populate the database.	
109:12 to 110:20	Price changes	First Data bank gets information from the manufacturers of their prices. There are tables that they have control over what goes out in the fields. They key in the information provided and then the tables derive what goes under the database with First Data Bank getting a quality control report. So they take the information they are provided, put it in and that tells them what is missing.	
112:24 to 114:9	Price information	The data entry people are going to key in the information and is done on a daily basis. It is usually processed within 24 hours from receiving it. Sometimes they receive price increase	

Page: line	Topic	Summary	Key Questions
		notification in advance.	
115:9 to 115:15	QC analysis	The data entry person runs the QC analysis on the computer and it tells them what fields are not populated that may have been populated in the past.	
117:6 to 118:25	Did not change markup at all	There is no standard for an AWP. It is average wholesale price. It goes into the bluebook field. So there is a wholesale net field, a direct price field, a bluebook field and an SWP (Suggested wholesale price.) So if Dey sends that price in and they are on this markup where their bluebook AWP comes from the markup over WAC, but in this case they did not change their WAC, but have a new AWP, then it only goes to the SWP field. It does NOT go into the bluebook field. So it did not impact the bluebook price. It does not change the markup at all.	
120:4 to 120:20	AWP	First Data Bank does not let manufacturers control the AWP field. The fact that Dey put out a new AWP does not change her markup. If it doesn't change the markup, she is not going to increase the bluebook AWP. Unless they increase their WAC.	
120:21 to 121:25	Checking	If somebody asks her to do a check, she does a survey. She'd call McKesson, Bergen and Amerisource and gives them labeler ID. Then she asks if they have changed the markup. She does it by manufacturer, not by drug name.	
124:2 to 124:7	Lowering their WAC	First Data Bank verifies that it is somebody that is authorized to speak for Dey, if they tell you they are lowering their WAC or their wholesale net, that will get populated into the database as long as it is writing.	

Page: line	Topic	Summary	Key Questions
125:8 to 126:5	Markups	The markups can be a specific percent or it can be to use what the manufacturer is suggesting as their AWP. The wholesaler survey tells her to use what the manufacturer is suggesting as their AWP. And that is done by labeler also.	
126:19 to 127:11	SWP will become the bluebook AWP	So you can check to see if you are using whatever Roxane or Dey told you to use. And if you're going to use what the manufacturer suggests, then the SWP will become the bluebook AWP. And that is populated into the database and published or reported to their customers.	
130:8 to 130:11	Reimbursement	Not all state medicaid programs use First Data Bank pricing information in some manner to determine reimbursement.	
131:1 to 131:11	Calculate reimbursement	Some state medicaid programs use First Data Bank pricing information to calculate reimbursement. She has been aware of that since she began to work for First Data Bank.	
132:12 to 133:3	Different formulas	There is a publication put out by the pharmaceutical council that has different formulas for different categories of products. And they report on the Medicaids every year.	
140:7 to 140:25	Editorial policies	First Data bank reports data in faithful adherence to its editorial policies. Their user manuals discuss policies. They are made available to State Medicaid programs.	
142:15 to 143:5	Define AWP	They define the AWP or the bluebook field as the average wholesale price First Data Bank tells everyone that they use a wholesaler's survey to determine	

Page: line	Topic	Summary	Key Questions
		the AWP or bluebook price.	
143:11 to 148:9	Exhibit 372	This exhibit is a NDDF User Manual. It appears to be from 1992. It is not a recent manual.	
148:14 to 149:4	Exhibit 365	She has not seen exhibit 365 before or a document like it. It says "instructions for 1995-96 bluebook."	
151:25 to 153:14	Publication stopped	They (First Data Bank)used to publish a bluebook. That publication was stopped in 1996. She was told that manufacturers were sent that report annually. But she has nothing to confirm that.	
157:19 to 160:1	Pen and ink change	If First Data bank were to have received a report with a pen and ink change in it, they would ask the company to send an actual documentation confirming the change in wholesale net. If they could not get any confirmation, she would do nothing.	
163:21 to 164:20	"One S"	'One S' means do whatever the manufacturer says about AWP.	
165:11 to 165:18	Applying markup formulas	According to Morgan, no wholesaler has represented to her at First Data Bank that their markup on any company's WAC is more than 5 times.	
172:5 to 172:25	Current plus 2 years	They keep current records plus 2 years and discard after that current plus 2-year period.	
173:10 to 174:25	Getting the data into the system	In the ordinary course of business, they generally attach a cover sheet of their own that tells who entered the data and who checked the data and who did the third check. It would have all the identities of everybody that had anything to do with getting the data into your system. That preprinted cover sheet is filled out if some action to be taken on the database. If there is no action to be	

Page: line	Topic	Summary	Key Questions
		taken, they simply put those in the files.	
177:5 to 177:20	Cover sheet	The cover sheet will tell you who checked that information and it gets checked again. The calculations relating to the markup are in the computer, they are not on the cover sheet.	
178:14 to 179:3	Markup on NDC	The only way you would see the markup on the NDC is that a survey was done on the NDC level. It has to be marked on the system that that is different than the other ones.	
183:19 to 184:4	Being a national wholesaler	Wholesalers provide product to the retail industry. They are members of the NWDA -- national wholesalers -- wholesalers that provide it to the nation.	
185:8 to 186:3	Exhibit 374	She has seen this document before. It is from Dey Laboratories. They were introducing a new product and their strength on their Albuterol was different than what First Data Bank had from other ones. Whenever a strength expression does not match up what they have on the database, they have to assign new categories. They were involved in validating the potency for this product.	
189:19 to 190:14	Exhibit 375	It is a document signed by Russ Johnson. He is the one to sign the letters that are sent to First Data Bank with the information.	
191:7 to 191:23	New AWPs and old AWPS	In this exhibit there are also charts that Dey has got old AWPs and new AWPs. In each instance the new AWP has gone up.	
191:24 to 192:13	If a 'One S' company	If Dey is a One S company in First Data Bank's system, then First Data Bank would report the new AWPs that are specified in Exhibit 375. And if they are NOT a One S company, then	

Page: line	Topic	Summary	Key Questions
		every time they increase their WAC, their AWP is going up by the same proportion --the proportion that is in the computer. And if they are not a One S company, every time Dey lowers its WAC the AWP goes down by the same proportion that it is the computer.	
193:22 to 194:16	Margin between WAC and AWP getting greater	They key the information provided. If it sees that they didn't get something they contact them and ask if there is a new WAC or new AWP. If they get told no, there is nothing further for them to do.	If a manufacturer, like Dey, Warrick or Roxane, is a One S company, and if they report WACs to your company that are falling as prices go down, and if they don't' report AWPs that are falling, what, if anything, will First Databank do to avoid the margin between WAC and AWP getting greater and greater as the WAC falls?
195:5 to 195:10	Drugs at Abbott	When she was at Abbott, she was in the pharmaceutical division that did the oral primarily.	
196:11 to 196:23	Exhibit 376	She is the author of this document. It is an editorial to the price alert publication when it was still part of the First DataBank.	
198:3 to 198:13	AWPs are falling	When she wrote the article that the prices are falling, there were 30 pages of price revisions to the hospitals wholesale acquisition cost that were dramatic drops. So when the lowered those prices, the AWPs correspondingly went down.	
198:19 to 200:23	People complaining about falling prices	People were complaining about falling prices because they were saying they couldn't make as much money. That was not an issue of hers, the falling prices. She just reported the prices.	
200:25 to 201:20	Calls from hospitals	It was hospital pharmacies that were calling her and complaining that they could not make as much money.	

Page: line	Topic	Summary	Key Questions
203:6 to 203:17	She reports prices	Morgan reports prices. She does not interpret what they are going to so. She does not try to figure out who they are going to benefit. She just reports them.	
204:11 to 205:8	Does not write any more	She has not written any other articles regarding falling prices. The editorials are never approved and so she does not write them anymore.	
205:11 to 206:4	Exhibit 358	She has not seen this document before. It was an article provided by McKesson to its customers, pharmacies. It says that most McKesson customers used First Databank's AWP for third party billing. In almost every case retail prices will go up helping increase profit. She has no idea how the customers could make more money if they use First Data bank's AWPs.	
209:11 to 201:18	One S manufacture r	She does not recall a wholesaler ever telling First Data Bank that they were going to stop treating a manufacturer as a One S manufacturer and treat them as a markup manufacturer because WAC prices were falling but AWP prices were not.	
210:4 to 210:8	Change from One S to markup	IF a wholesaler wanted to change a manufacturer from a One S manufacturer to a markup manufacturer, all they have to do is call her and tell her.	
211:3 to 212:19	Exhibit 357	In this exhibit R. Hawley, General Counsel for Hearst corporation, is writing to D. Tooch of Hooper Lundy & Bookman, making statements about AWP. He says that "AWP is the price at which a particular drug is sold by pharmaceutical drug wholesalers to their pharmacy customers. It is her understanding that AWP is the price that can be charged when there is no existing business relationship.	

Page: line	Topic	Summary	Key Questions
215:10 to 216:1	First Data Bank does not let manufacturers set AWPs	She was copied on this letter, exhibit 357. She understood it that in the letter a company was saying that their list price was their AWP. The company alleged that the AWPS being reported by First Data Bank were not the AWPs that they set. The company said that First Data Bank was wrong. First Data bank does not let manufacturers set AWPs.	
216:2 to 217:1	Exhibit 356	Exhibit 356 states that "what is important for the purposes of medicaid reimbursement is the actual price at which a product is sold by wholesalers to their customers. That price is AWP and it is reflected as accurately as possible by the surveys conducted by First Data Bank."	
218:20 to 219:12	Reduce pricing	Other than the 4 items of information: AWP, direct price, wholesale net which becomes WAC, and suggested wholesale price from the manufacturers, there is other pricing information available. She is aware that 2 companies - Taft and Bayer have been asked to provide ASPs - average selling prices to the states.	
222:15 to 223:4	Primary and secondary wholesaler	No. But people choose normally a primary wholesaler and a secondary wholesaler. If your primary and your secondary wholesaler can't supply you and you're going to somebody else you are going to pay AWP.	Do you know whether the major wholesalers today make it easy for customers to develop a relationship with them so they can purchase for less than AWP?
224:7to 225:8	Exhibit 377	This is a price alert, dated March 15, 2000. She wrote this one but it was finalized by Elaine Kiso and Pat Muller when Morgan was out of town. It was	

Page: line	Topic	Summary	Key Questions
		reviewed and published.	
225:9 to 226:10	AWP defined	In the article it states that AWP is the average wholesale price. AWP is the average of prices charged by the National Drug Wholesalers for a given product (NDC) and referred to by First Data Bank as 'bluebook price.' In order to determine AWP, First Data Bank surveys national wholesalers to ascertain what the price is. This is based on their AWP price files. First Data Bank contacts the wholesalers to determine what the markup should be for a new company. First Data Bank then confirms that the markup is accurate and current.	
226:11 to 226:19	Determine appropriate AWP	A survey maybe performed on a single NDC number or on a manufacturer's entire product line. A survey will be performed with all national wholesalers to determine the appropriate AWP.	
226:23 to 227:7	Wholesaler's AWP	When the wholesaler says use the AWP that the manufacturer suggests, then that is the wholesaler's AWP.	
230:15 to 231:16	Manual	The manual provided to the customers are maintained by a documentation area. It is located in Indianapolis.	
233:20 to 234:25	Look for old copies of editorial policy	If she were to physically go to find the documentation of editorial policy form the time she began with the company forward she would just look for current copies. They are in their computers, on the server. So they know the current policy and can print them out at any time.	
237:18 to 237:24	Joe Palermo	Joe Palermo was the highest ranking person in the company that gave her any directions regarding document control and retention.	
		Examination by Mr. Breen:	
239:13 to	Exhibit 378	This consists of 8 terms regarding pricing in this lawsuit:	

Page: line	Topic	Summary	Key Questions
240:8 240:23 to 241:5		Wholesale cost Wholesaler cost Price to wholesaler Wholesale acquisition cost or WAC Wholesale net Wholesaler net cost Wholesale price Wholesale acquisition price She considers all of them a synonym industry jargon to reflect the price charged by the manufacturers to the wholesaler.	
240:9 to 240:22	WAP = WAC	Wholesale acquisition price is synonymous with wholesale acquisition cost	
242:5 to 245:23	243:12 to	The report, "Price History Report" lists Dey, Zenith, Goldline, Roxane. Whoever is querying them is also pulling up information on other manufacturers as well.	
246:12 to 248:4	Price History	The Pricechek and the First Data Bank are fed by Master databases. The price history is the current price plus seven on the unit price. When the 8th history comes on line in the database, the oldest one is dropped. It goes somewhere but she is not sure where.	
253:10 to 253:12	Owner of First Data bank	Hearst corporation is the owner of First Data Bank	
257:3 to 257: 10	Interaction of bluebook with database	There is a field on her database called Pubex. It is an exclusionary code for bluebook. She asked them to get rid of that since they don't have bluebook but it is still there.	
258:9to 258:25	Bluebooks in archives	There is a bookshelf, floor to ceiling tall, 3 feet wide, of the bluebooks at First Data bank.	
259:1 to 259:5	Hearst owned	Hearst owned the bluebook. Then acquired First Data Bank.	

Page: line	Topic	Summary	Key Questions
	bluebook		
259:20 to 263:2	Exhibit 379	This exhibit is a pricing data price confirmation form and is a communication between Dey and First Data Bank. It is a fax generated from Dey to First Data Bank that First Data Bank sent back.	
270:2 to 270:13	Information compiled in the database	The information complied in her database is: AWP WAC SW Direct price. They do not compile MACs because MACs are customer driven by their own algorithms and they don't have any MACs.	
270:25 to 271:18	MACs	MACs used to be what was set by the federal government in 80's. They became Federal Upper Limits. There are states that have MAC pricings for which First Data Bank does their formularies, so there is a product that is sold that has state MACs in it, but it is done by the states. It is not something they establish or set. There are some states who actually pay First Data Bank to get updated MAC arrays or Mac information -- manage their data.	
272:4 to 272:9	Pay First Data Bank for information	One state could subscribe to information that would provide them another state's MAC information. They would just have to pay First Data Bank for it.	
273:5 to 273:11	How Federal Upper Limit Applies	The Federal Upper Limit does not have to be respected by a state with respect to a given product. It is simply a requirement that the state stay within the aggregate limits that are calculated	

Page: line	Topic	Summary	Key Questions
		using the Federal upper limits for the total products, on the formulary.	
273:16 to 274:15	How federal upper limit applies in the medicaid programs	The Medicaid program, the drug part, is an optional part. States are not required to offer a drug benefit, but all states do at this point in time. The funding of the program is shared between the federal government and the state government depending upon a formula that they have. California is 50/50. Illinois is 50/50. Her understanding of the upper limit is that at the end of the year, their upper limit would have been applied to how much they had spent on those products and as long as the total bottom line matched what the feds said they should spend or was less, they will get their match. If they exceed the amount they should spend they do not get their matching money.	
274:16 to 275:1	Guideline on reimbursement	If a state wanted to observe a federal upper limit with respect to a particular product, that would be something that would be optional. And the federal upper limit with respect to a particular product would be a guideline on the reimbursement for that product.	
276:24 to 277:17	Exhibit 380	This exhibit is a resolution text. It is a free text area. You can type in anything. You are not constrained by the database as to what can go in there. It did not come from the First Data Bank file.	
279:17 to 281:9	Medi-Span	This exhibit is probably a Medi-span document. The merger with First Data Bank occurred in 1998. The divestiture was December 19, 2001.	

Page: line	Topic	Summary	Key Questions
		Some people were assigned to the new Medi-Span company in the divestiture -- customer support, some salespeople, some of the computer people. Medi-Span was acquired by Facts & Comparisons. They are in Indianapolis.	
281:18 to 282:24	Tom Bizarro	Tom Bizarro is the person at Medi-Span that had the position that was comparable to Morgan's. He is still at First Data Bank in Indianapolis.	
282:25 to 283:9	Quality control	The Quality Control function within First Data Bank has bee in existence for a long, long time.	
283:10 to 284:15	Human error	There have been errors -- human error -- made by staff at First Data Bank. On an average day, they deal with 600 changes. Or it can go up as high as ten times that amount.	
285:19 to 286:13	Dosage	When talking about cost to the payer it is important to recognize that you are not just considering the cost per tablet of the medication, but the actual cost per medication. The frequency of dosage is important. All of her customers consider the total cost of care versus just the published price.	
287:17 to 288:3	Benchmark price	Most agree that AWP is the benchmark price.	
288:13 to 289:11	Spread	Spread is a measurement of differential.	
291:20 to 292:9	Master database	She populates a master database. A lot of those files are driven by algorithms. An algorithm is a code word meaning a formula to crunch information.	
292:10 to 294:10	Clinical information	Clinical information refers to more than the type of drug.	
295:19 to	Location	First Data Bank still maintains the Medi-span database under an	

Page: line	Topic	Summary	Key Questions
295:24		arrangement that is permissible. The data is entered in San Bruno, California. The actual computer, is in Indianapolis.	
296:58 to 296:22	Subscribe to data from First Data Bank	If a medicaid payer, a state government, wants to subscribe to data from First Data Bank, in order to do that they are going to have to have a customized interface to see, receive and interpret the data. There is no uniform report that is provided electronically. Therefore any medicaid customer can work with First Data Bank to get whatever information they choose to get or not to get.	
303:19 to 304:9	Exhibit 369	Exhibit 369 is an letter from Dey addressed to Kathy Gutgesell. She is a former employee of First Data Bank. The letter is dated 12/31/97 -- a pricing list that First Data Bank would routinely receive for updates from any given manufacturer.	
304:10 to 305:7	Exhibit 381	Is a Pax ticket. It is a Medi-Span document. It is what is sent from customer support to the relative areas regarding something on the database. It keeps track of questions that are raised, or shipping, more data or anything similar that comes to customer support. It is a tracking system.	
306:3 to 306:25	Exhibit 382	Connie Westbrook was employed in Indianapolis, prior to the merger. She was employed by Medi-Span. She is no longer there.	
307:1 to 307:10	Exhibit 383	It is a letter from a former employee of Dey addressed to Mr. Edelstein, a former employee of First Data Bank.	
307:20 to 308:24	Exhibit 385	It is a Medi-Span problem ticket profile. Prior to the merger, Medi-Span had an independent system for verification of AWPs at any point in	

Page: line	Topic	Summary	Key Questions
		time. Even after the merger the were records that would reflect a different AWP for a particular drug than would be reflected in the First Data Bank's records. The difference could be a lot of things: A keying error Data not getting into all of the databases A markup difference not noticed by the person doing the data	
308:25 to 309:15	What manufacturers do not control	Manufacturers do not control First Data bank's AWP listings. And manufacturer's do not control the markup. They are looking to the wholesaler for the ultimate information.	
310:19 to 311:3	Definition of wholesale acquisition price	The definition of wholesale acquisition price is the published price from the manufacturer to the wholesaler.	
311:4 to 312:21	Exhibit 386	This exhibit is a transcript of Ms. Morgan's ½8/02 deposition, examined by the Texas Attorney General's office.	
313:17 to 313:22	Not every change prompts a survey	Note every change in reported WAC to first Data Bank is going to prompt a survey. And if there is no survey, then the previous markup will continue to apply.	
315:5 to 315:15	New AWP	If there is a markup that is recorded in the system already and a manufacturer reports a new WAC for a product, that will drive a new AWP, as long as it is not One time S.	
317:17 to 318:22	Problems blamed on computer	The computers are pretty reliable. A lot of times the computer gets blamed, whether it is a keying error or misinterpretation. There are 2 separate entry levels: One when the information is initially	

Page: line	Topic	Summary	Key Questions
		entered into the tables and then the second level of information entry is when the information is keyed into the fields, based on the tables. It is the first step.	
319:3 to 321:9	Process of setting it up	First you have to initiate a file by setting up the chemical entity: dosage, form, active ingredient, route and strength. Then there's the entry of the actual product data -- the NDC, label name, the brand name, several of those things. Then there is the maintenance of that record, the pricing updates. From one system they are put into an editor card and then the editor card is transferred to the message libe and G message libe to the master database and the database is run. The data is entered by one person. They give the information in the hardcopy to a person who checks their work. And they have to do it on all 3 databases. The second person checks their work on all 3 databases. They transfer the data -- First Data Bank files to what is called a G message libe. Then there is the person that actually runs the database who runs the QC to make sure that they didn't put any strange things in the file. Then it goes to the person that runs the large database at night. The next morning a person comes in that is assigned to check the database and they go through and look a third time for any mistakes.	
321:12 to 321:18	3 databases	The 3 databases are: First Data bank Medi-Span	

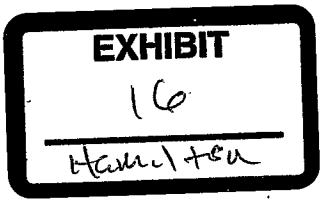
Page: line	Topic	Summary	Key Questions
		PIF (product information file)	
322:16 to 322:23	Mark Hogan	Mark Hogan is in charge of the end product of the database in St. Louis.	
323:3 to 323:6	GPOS	GPOS -- group purchasing organizations, generally relate to a group of hospitals.	
329:17 to 329:24	Conferences	At the seminars sponsored by First Data bank, specific pricing is not discussed. It is absolutely forbidden. Price concepts are not discussed at all.	
332:1 to 332:24	Wholesale net	Of the 264 some-odd thousand products that she has on the database, about 42% of those have the WAC field populated. If you start excluding the things that make no sense, they get up over 90% of the products have WACs.	
333:19 to 334:1	AWP is a benchmark	AWP is a benchmark. It is a price that people know what the defined value depending on the database you are using, what it is. They use that as the point from which they do the negotiations for which they will reimburse.	
334:18 to 335:13	Dept. of Justice proposed certain medicaid AWPs.	She did hear complaints from Medicaid agencies at the state level because they assumed that he had not populated the price field correctly. The complaint she got was that she did not have her AWP field, bluebook field populated properly. They would have a different price than she would.	
335:23 to 336:25	Complaining about prices	She spoke at the National Medicaid meeting and the ACS meeting -- a provider of data from medicaid -- that they are unable to obtain those products at those prices. The people that work for the state medicaids told her that. They said they had people complaining that they cannot obtain the products at	

Page: line	Topic	Summary	Key Questions
		those prices because they are too low.	
342:23 to 343:7	Competition in the generic market	Competition in the generic market is not only based on price but ability to supply, reputation, number of recalls.	
		Examination by Mr. McDonald:	
345:9to 346:1	Warrick provided WAC pricing	Within the past 6-8 months, Warrick reported a product. There was no wholesale acquisition price. Warrick said they were not going to provide it. First Data bank said then they weren't going to report the product. Later Warrick provided the WAC pricing.	
347:3 to 348:3	No written policy	Once a markup is in place for a manufacturer, First Data Bank has not backed into a WAC price once it has an AWP. First Data Bank does not have a written policy to make such a calculation.	
348:4 to 348:25	Exhibit 387	She has not seen this exhibit before.	
349:10 to 349:25	Get it in writing	In order for First Data Bank to list a WAC or wholesale net price, it has to receive written documentation from a manufacturer or wholesaler. Sometimes they get caught in a time frame and it will get in on the database today, and they can send it in writing momentarily. If she does not get it in writing, it will be backed out.	
350:7 to 352:1	Where information came from	Based on the definition of the field "published price from the manufacturer to the wholesaler", it always comes from the manufacturer. No matter the route, it always comes from the manufacturer.	
354:7 to 355:3	Populate both fields	If a manufacturer did not give her a WAC price but gave a direct price, First Data Bank would populate both the direct field and the WAC field with that price because the manufacturer is the direct customer as well. The	

Page: line	Topic	Summary	Key Questions
		wholesaler is. And they look at the data they are provided and try to make it fit the fields the best they can.	
		Examination by Mr. Hagenswold:	
356:21 to 357:25	Rich Feldman	Rich Feldman is a name she associates with Roxane. He is with Boehringer Ingelhiem. He is the director of trade relations for Boehringer. Morgan did trade for Abbot Labs for about 6 years. He is the one that submits the information to First Data Bank from Boehringer. She talks to him periodically but has had more interaction with him when she was Abbott.	
		Examination by Mr. Anderson:	
358:8 to 359:4	AWP gets listed	If a manufacturer does not have a wholesale net price listed with First Data Bank, First Data Bank has an AWP for that manufacturer's product in the database for many reasons: They could be a repackager or private label or it could be a device manufacturer that is not going through that market. Or historically some manufacturers have not provided it. The wholesaler went along with using their suggested AWP and that is how it got populated.	
362:12 to 362:17	NDDF user manual	Other than the NDDF User Manual, there is no other documentation of First Data Bank's editorial policies.	
		Examination by Mr. Breen:	
363:25 to 364:17	Exhibit 379	The second page of this exhibit is one page of the screen. It he wanted to find out whether this one was a One S manufacturer or a specific NDC number One S, he could calculate it from the screen but it is best to go to the table (the basic database that the screen will draw from) from which it	

Page: line	Topic	Summary	Key Questions
		populates the screen. So it would be easy to find out what was going on with Roxane by checking the table.	
365:3 to 365:5	Reporter	First Data Bank is a reporter, not a creator.	
366:7 to 366:17	Always survey	They always survey the wholesalers. If they say to use what the manufacturer suggested, that is what they will use.	
368:13 to 368:19	Drug manufacturer's AWP	With the One S field, you are using the drug manufacturer's suggested AWP.	
370:22 to 371:1	SWP and bluebook SWP	She does not have any data available that would indicate the percentage of times that the SWPs are the same as the bluebook SWP.	
371:15 to 371:25	Not calculated WACS	During her time with First Data Bank, they have not calculated any WACs from AWP.	
		END OF DEPOSITION.	

GLOBAL MARKET RESEARCH
HEMOPHILIA



MRB April 2002

Price Monitoring

SURVEY ON HEMOPHILIA CARE

& PRICE MONITORING

UNITED STATES

WAVE # 10

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April 2000

TABLE OF CONTENTS

LIST OF TABLES AND CHARTS

EXECUTIVE SUMMARY

* *Recombinant Factor VIII and IX concentrates continue to make inroads into the U S market According to this survey wave, about 80% of the patient population sampled used this type of clotting Factor concentrates In the past twelve months, both rec ombinant Factors VIII and IX increased their market penetration by about ten percentage poin s*

* *Although the shortage of Factor VIII products was not as acu.e in 1999 as it was in 1998, many hemophilia patients had to switch from one product to anc ther within a category (rFVIII or monoclonal antibody-purified), and the preferred vial size was often unavailable As regards Factor , AlphaNine SD was in short supply but the volu ne of Mononine available was higher than in the previous year The 1998 shortage of Aventis Behring's Humate P was virtually over in 1999*

* *In 1999, Baxter's Recombinate maintained its leadership among the recombinant Factor VIII concentrates, as 42 3% of the patients in the sample used this product, representing a 6 8 percentage points gain in the last twelve months Bayer's Kogenate followed with 23 6%, a 1 3% gain over the same period one year ago Aventis Behring's Bioclate went from 4 0% to 4 8%, and the share of Helixate, from 6 1% to 7 1% of the pa ient population in the sample The American Red Cross' Monarc-M and Baxter's Hemo ii-M both posted decreases, recording shares of 8 5% and 10 5% respectively Aventis Behring's Monoclate P lost 0 6 percentage points to 2 7% market share The share of the "intermediate purity" products, Alpha Therapeutic's Alphanate and Bayer's Koate DVI (or HP) went down from 0 5% to 0 4% (Koate), and from 0 7% to 0 1% (Alphanate) respectively*

* *On the Factor IX Market, BeneFIX captured 79 9% of the hemophilia B patients in the sample, the remainder using Mononine (13 9% market share, or +5 5%), as AlphaNine SD was in short supply (5 9%, or -20 2%) The shortage of virtually all Prothrombin Complex concentrates led to substantial decreases of the market share of this product category which was now below 0 5%*

* *The approval of Aventis Behring's Humate P for the treatmer t of von Willebrand's disease (vWD) and its higher supply in 1999 was a great relief for the vWD patients who had been affected by last year's shortage As a result of the efforts of the National Hemophilia Foundation and other groups to identify individuals with von Willebrand's disease, a larger number of patients were registered by the treatment centers Ir a shift from earlier years, the shortage of Alpha Therapeutic's Alphanate led some patients tc use Bayer's Koate DVI/HP to treat vWD*

* *According to the survey results, approximately one third of the hemophilia patients with high level inhibitors are subjected to an immune tolerance regimen, and this was unchanged from last year Approximately 20% of the inhibitor patients were reported to be using NovoSeven the newly approved recombinant Factor VII a from Novo Nordisk. 40% of the patients in the sample were reported to be using Baxter's Feiba VH, and some 11% of the patients Nad a Autoplex T which gained two percentage points Speywood's Hyate C (porcine Factor VIII continued to be used in complicated situations, usually after the other products did not control a bleed. Due to the short supply, or virtual unavailability of Konyne 80 and Profilnine SD through most of 1999, the use of these Prothrombin Complex concentrate in inhibitor patients was virtually abandoned although Bebulin VH was occasionally prescribed. Proplex T is now almost entirely reserved to Factor VII-deficient patients*

* *A progression of primary and secondary prophylaxis was noted in the past twelve months reaching 14 3% of the patients, a 2 8% growth from last year Approximately two thirds of them were under secondary prophylaxis, and one third under primary prophylaxis*

* *In 1999 and early 2000, the FDA approved several concentrates, new formulations or re indications for existing products*

  - *Aventis Behring's Humate P for the treatment of von Willebrand's Disease,*
  - *Bayer's Koate DVI, which added a new virus inactivation step to Koate HP*
  - *Novo Nordisk's NovoSeven (recombinant Factor VII a), and*
  - *Wyeth Ayerst's ReFacto (recombinant Factor VIII)*

* *The gene therapy trials for hemophilia A or B continued to fuel the hope of patients for a cure although it was realized that this mode of treatment is still five years away the trials of Chiron and Transkaryotic Therapies (TKI) for hemophilia A, and Avigen for hemophilia B made the front page of the specialized press, especially in early 2000 when "stop and go" events occurred. The situation seems to have stabilized by now*

* *In the past twelve months, the acquisition prices of almost all coagulation factors increased slightly whereas the reimbursement prices of most products posted a modest decline. The Average Wholesale Price of several clotting Factor concentrates were increased in 1999 offering higher reimbursement rates to home care companies*

* *During the period under review, Caremark Therapeutic Services, Gentiva Health Services (formerly called Olsten Health Services) and Hemophilia Health Services (HHS) remained the dominating home care companies with membership ranging from 800 to 2 500 hemophilia*

patients This sector continued to be highly competitive, making it possibly less attractive than a few years ago, despite the higher reimbursement rates in part to the lower difference between the acquisition and reimbursement prices Home care companies are also subjected to tighter pricing from than they used to be

* *In 2000, the return to the market of Aventis Behring on the U S plasma-derived market may result in a stabilization of the market shares of the recombinant Factors VIII and IX, and contribute to a more ample supply of clotting Factors overall. The continued progress of primary and secondary prophylaxis, and the increased clotting factors usage of young patients gaining weight as they grow up will contribute to the market growth in volume This growth may be in the 5% to 10% range, as it was in 1999 The increased demand will be met be the growing supply of the recombinant and plasma-derived products, as more capacity becomes available The acquisition prices will probably increase moderately, as they did in 1999 The number of centers adopting the provisions of the VA Bill is not expected to change significantly because those centers which decided to opt for it have now done so Several product approvals may occur, in particular Alphanate (Alpha Therapeutic) for the von Willebrand's Disease indication, and Kogenate SF Baxter's new Recombinate is not expected to be on the market anytime soon*

HEMOPHILIA CARE AND PRICE MONITORING

Wave #10, January 2000

1) INTRODUCTION

1 1) General Observations & Data

The use of recombinant Factor VIII and IX concentrates accounted for about 80% of the patient population sampled in this survey wave, comprising approximately 3,300 hemophilia A and 1,100 hemophilia B patients This result confirms the growing acceptance of these products which began seven years ago in the United States In the past twelve months, both recombinant Factors VIII and IX increased their market penetration by about ten percentage points

Percentage of Patients in the Sample using recombinant Factors VIII and IX

Product	January 2000	January 1999	January 1998	Change '00/'99
Recombinant Factor VIII	77 9%	67 9%	63 4%	+10 0%
Recombinant Factor IX	79 9%	70 4%	43 6%	+9 5%

During the year the shortage of recombinant Factor VIII products compelled many hemophilia A patients to switch products, sometimes several times in the course of the year, depending upon availability In many instances, the adequate vial size was not available, leading to possible waste of some product Nevertheless, those hemophilia patients who elected to undergo immune tolerance induction or prophylaxis were able to obtain the rFVIII they needed, and no interruption of such protocol was reported for lack of product Similarly, no report of delayed or canceled elective surgeries were reported among the centers surveyed

As was observed last year, the supply issue remains a critical one in the opinion of many survey respondents, although to a lesser extent than last year This may be attributed to a more ample supply of rFVIII, partially due to Baxter's higher manufacturing capacity Throughout 1999, several published reports have stated that Bayer and Baxter could not keep with the demand, both in the United States and overseas, which is hardly surprising if 80% of all patients use this type of product, and at a volume level per patient which is higher than ever before

The approval of Wyeth Ayerst's *ReFacto* made by Pharmacia & Upjohn in Stockholm, Sweden, is expected to only partially alleviate the shortage of rFVIII in 2000 as its supply is believed to be

relatively limited, at least initially Furthermore, Baxter's additional manufacturing capacity at its Thousand Oaks plant will increase the supply of *Recombinate*

On the Factor IX scene, no shortage of Genetics Institute's *BeneFIX* was reported The shortage of Alpha Therapeutic's *AlphaNine SD* contributed to *BeneFIX* further advance and Aventis Behring's *Mononine* gained 5 5 percentage points As Bayer's *Konyne 80* and Alpha Therapeutic's *Proplex SD* were both in short supply, the share of the Factor IX complex concentrates or Prothrombin Complex concentrates (PCC) dropped to less than 0 5%, a sharp drop from two years ago (January 1998) when their combined market share was 12% For those patients with an inhibitor who were treated with these products, the approval of Novo Nordisk's *NovoSeven* in April 1999 offered much needed relief The survey showed that *NovoSeven* captured 20% of the inhibitor patients not only at the expense of the PCC but also of Baxter's *Feiba VH* (-2 points) while Nabi's *Autoplex T* gained one percentage point Speywood's *Hyate C* maintained its position as the treatment of last resort for complicated inhibitor situations

The approval of Aventis Behring's *Humate P* for the treatment of von Willebrand's Disease patients (June 1999) was a relief for these patients, as the product became more readily available than in 1998 The survey showed that some centers were now using Bayer's newly approved (May 1999) *Koate DVI* to treat vWD possibly because of *Humate P*'s shortage earlier while others continued to use Alpha Therapeutic's *Alphanate*

1 2) Contemporary Issues and Patients Concerns

In 1999, the shortage of products did not appear to be as acute as it was in 1998 although the unavailability of certain vial sizes was emphasized by a number of respondents

The rising awareness of hepatitis C, uncovered by improved testing was mentioned by some survey respondents Although the treatment combining Ribavirin and Alpha-Interferon represents a definite progress, patients have to worry about their enzyme level and undergo liver test regularly even though they may not be symptomatic This problem concerns more the older patients who use plasma-derived concentrates than the younger ones even though there has been no HCV seroconversion among hemophilia patients since 1993

The issue of the risk of transmission of the Creutzfeldt Jakob Disease (CJD) through blood products appeared to be less acute than in 1998 This stemmed perhaps from the FDA's decision (August 27, 1998) to end the recalls and withdrawals of plasma derivatives made from donors who died from "classic CJD", received a dura matter transplant, or received growth hormone made from human pituitary glands Reports on the perception of this risk by hemophilia patients suggested that

many would consequently not switch to an albumin-free recombinant concentrate although testimonies from several treatment centers treating primarily pediatric patients indicated that the young hemophiliacs and their parents would switch anyway in order to be at the maximum safety level

Throughout 1999, the FDA continued to exert close scrutiny ove the fractionators In January 1998, Alpha Therapeutic agreed to enter a Consent Decree with the Government while other companies were subjected to a number of corrective measures The American Red Cross, which was still under a Consent Decree from the late 1980's, was less affected after having suffered numerous products recalls and withdrawals related to CJD in earlier years

On the positive side, the HIV positive and hemophilia patients and those with AIDS were reported to enjoy a much better health status thanks to the multiple therapy involving Proteinase Inhibitors These patients were reported to feel stronger and enjoy a level of well being which they had not experienced in a long time Some were able to return to work or to school, and their life expectancy increased significantly In 1999, the issue of HIV was still in everyone's memory, but legal action on this matter seemed to gradually fade away in importance

The hemophilia patient population now comprises three main segments

- Those who use recombinant Factors VIII or IX, and who are typically young patients, generally HIV negative Many of them were born after 1992 and never infused a plasma-derived product, and they may never need to do so if they do not develop inhibitors

- Those who still use a plasma-derived concentrate Generally older, sometimes pressured by cost constraint, the need to switch to a recombinant product does not appear as a priority for them, for medical, financial or personal reasons They are still comfortable with the product they have used for many years, and do not wish to change In some cases, the shortage has forced some of them to switch The number of those who switch back to a plasma-derived product, such as *Monoclate P* or *Mononine* did not appear to be significant in 1998 but slightly did grow slightly towards the end of 1999 when the Aventis Behring products became widely available again

- A third category of patients appears increasingly important in the blood disorders community individuals, men and women, suffering from von Willebrand's Disease In the past two or three years, several organizations, in particular the National Hemophilia Foundation, have emphasized the needs to better diagnose and treat persons with vWD The survey showed that many centers had made special effort to better locate and diagnose these patients

In the past two years, the priorities have clearly changed in the hemophilia community While the compensation of HIV positive patients and the Ricky Ray bill were among the main issues debated during the 1990's, and were at the origin of the creation of such advocacy groups as the "Committee of Ten Thousand" (COTT), a new era began in 1998 with the settlement offered to HIV-positive patients and the adoption of the Ricky Ray bill Today, COTT the National Hemophilia Foundation, the "Coalition for Hemophilia B" and other groups such as the "Hemophilia Federation" take a new course and advocate causes that are newly relevant among their constituency For instance, the NHF is now emphasizing a new program aiming at finding a cure for hemophilia

It is generally accepted that blood products are now safer than ever, in particular under FDA's closer scrutiny The safety issue does not draw as much attention as it used to in particular among the many patients who use recombinant products For this reason, many respondent indicated that the albumin-free recombinant Factor VIII would not necessarily be adopted promptly at their center and its acceptance would largely depend on its price Today, the question is not only to get a safe product, regardless of the cost, but to get product in the first place, and preferably in the right viral size Nevertheless, many problems continue to be faced by hemophilia patients, such as hepatitis C and other health concerns The cost of clotting factors remains a major problem encountered by families with a hemophilia patient, even if the situation seems to be better than a few years ago The health insurance lifetime cap which many insurance companies impose on their customers is another issue which may become crucial at time passes

1 3) Community Service by the Manufacturers of Clotting Factors

The survey addressed the question of the perception of the various manufacturers in terms of community service and image While a number could not rank the companies because they used only one or two of them, those who volunteered some impression indicated that Genetics Institute Baxter, and to a lesser extent Bayer, were on top of the list The American Red Cross did not get the best mark, a situation which may change with its newly launched "Care 2000 campaign" Due to their absence from the market, Alpha Therapeutic and Aventis Behring were usually ignored In many cases, the personality of the company representative was reported as playing a prominent role on the way it was perceived by the HTC staff This was particularly the case for the home care companies which have a more direct involvement with patients

2) NEW PRODUCTS AND THERAPIES FOR HEMOPHILIA

2 1) Gene Therapy

In 1999, three companies undertook gene therapy for the treatment of either hemophilia A or B Respondents to the survey indicated that there is a keen interest in this type of procedure on the part of the patients or their parents, but that there is also an understanding that it is not a total cure, that it will only reduce the severity of hemophilia, and that it is still several years away from general access The issue of its possible cost was not brought by any of the respondents Three clinical trials of gene therapy are currently under way As the subject is amply covered by the medical and hemophilia press, the summary below is concise and not technical

Hemophilia A

- *Transkaryotic Therapies (TKT)* initiated the first clinical trial at the end of 1998, using a "ex vivo" technology according to the protocol, skin cells are taken from the patient, hemophilia A genes are inserted into these cells, and they are subsequently returned to the patient, ready to produce the missing Factor VIII The trial is conducted at Beth Israel Deaconess Medical Center in Boston It was temporarily halted in February 2000 following the death of a young individual who was treated at another center with gene therapy for a different kind of disease (Ornithine Transcarbamylase, OTC) caused by a deficiency of a liver enzyme, unrelated to hemophilia

- *Chiron Corporation* started its clinical trial at the University of Pittsburgh Medical Center in June 1999, and it is performed at three additional centers, at the University of California, Davis, Harvard University, Cambridge, and University of North Carolina, Chapel Hill Chiron technology consists in a direct administration of the Factor VIII gene into the patient's system

Hemophilia B

- *Avigen*, a company based at Stanford University in California, has developed a product called "Goagulin B" which enables the production of Factor IX when administered to the patient by intramuscular route This procedure is presently tried at Children's' Hospital in Philadelphia It Among others, it shows that Factor IX is not exclusively generated by the liver

It is generally believed that the commercial exploitation of these therapies is at least five years away

2.1) New Concentrates approved in 1999

In 1999, the FDA granted the following products approvals

1) At the end of March 1999, Novo Nordisk's "NovoSeven" recombinant Factor VII a was approved by the FDA, and was immediately commercialized NovoSeven is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factors VIII or IX. The product is manufactured and stabilized without the use of human albumin or other human-derived proteins The recommended dose is 90 mcg/kg of body weight given as intravenous bolus every two hours until hemostasis is achieved. Depending on the type and severity of the bleed, "NovoSeven" has been demonstrated to be efficacious in 90% or more of patients There are no age restrictions on its use, infants as young as ten days old have been treated successfully in clinical trials The average wholesale price was set at $1.40 per mcg

   A voluntary "NovoSeven Cooperative Registry" post-marketing surveillance program was established to collect additional data on the adverse effects profile of the product and to monitor the frequency of any thrombolytic events

2) In May 1999, Bayer (Biological Products) announced that the FDA approved a Product License Amendment for its new "Koate-DVI", a high-purity antihemophilic factor featuring "Double Viral Inactivation" Independent solvent-detergent and dry heat viral inactivation steps are used to enhance the theoretical margin of safety of "Koate-DVI over Bayer's long-lived "Koate-HP" plasma-derived product A 72-hour, 80°C dry heat processing step was added to the Tween 80/TNBP solvent/detergent treatment used to inactivate lipid-enveloped viruses, "further increasing the margin of safety of an already safe product."

3) In June, the FDA approved an additional indication for Aventis Behring's Humate-P a plasma-derived Factor VIII concentrate containing von Willebrand Factor the treatment of severe cases of von Willebrand's disease

4) In February 2000, Genetics Institute's *ReFacto,* a new recombinant Factor VIII concentrate was approved for marketing in the U S *ReFacto* differs from the other recombinant Factor VIII products by the absence the B-domain of the Factor VIII molecule Furthermore it is the first rFVIII product formulated without the addition of human albumin as a stabilizer *ReFacto* is indicated for the control and prevention of bleeding episodes and surgical prophylaxis in patients with hemophilia A, and it is indicated for short-term routine prophylaxis to reduce the frequency of spontaneous bleeding episodes

Table 1

HEMOPHILIA CARE AND PRICE MONITORING

IN THE UNITED STATES WAVE #10 - JANUARY 2000

THE COAGULATION FACTOR CONCENTRATE MARKET - USA - 1999

Market Penetration of the recombinant Factors VIII and IX Concentrates in the United States

(Percent of Patients in Sample)

Product	January '00	January '99	January '98	January '97	April '96	Sep '95	Dec '94	Dec '93
Recombinate	42 3%	35 5%	32 6%	35 7%	36 8%	29 8%	17 0%	9 6%
Kogenate	23 6%	22 2%	21 5%	14 8%	9 4%	14 5%	19 3%	6 9%
Bioclate	4 8%	4 0%	6 3%	4 7%	5 1%	2 2%	0 5%	0 0%
Helixate	7 1%	6 1%	3 0%	2 4%	1 2%	2 1%	0 0%	0 0%
Total	77 9%	67 9%	63 4%	57 6%	52 5%	48 6%	36 8%	16 5%
BeneFIX	79 9%	70 4%	43 6%	NA	NA	NA	NA	NA

Chart 1

MARKET PENETRATION OF rFVIII 1993 - 2000 (Percent of Patients in Sample)

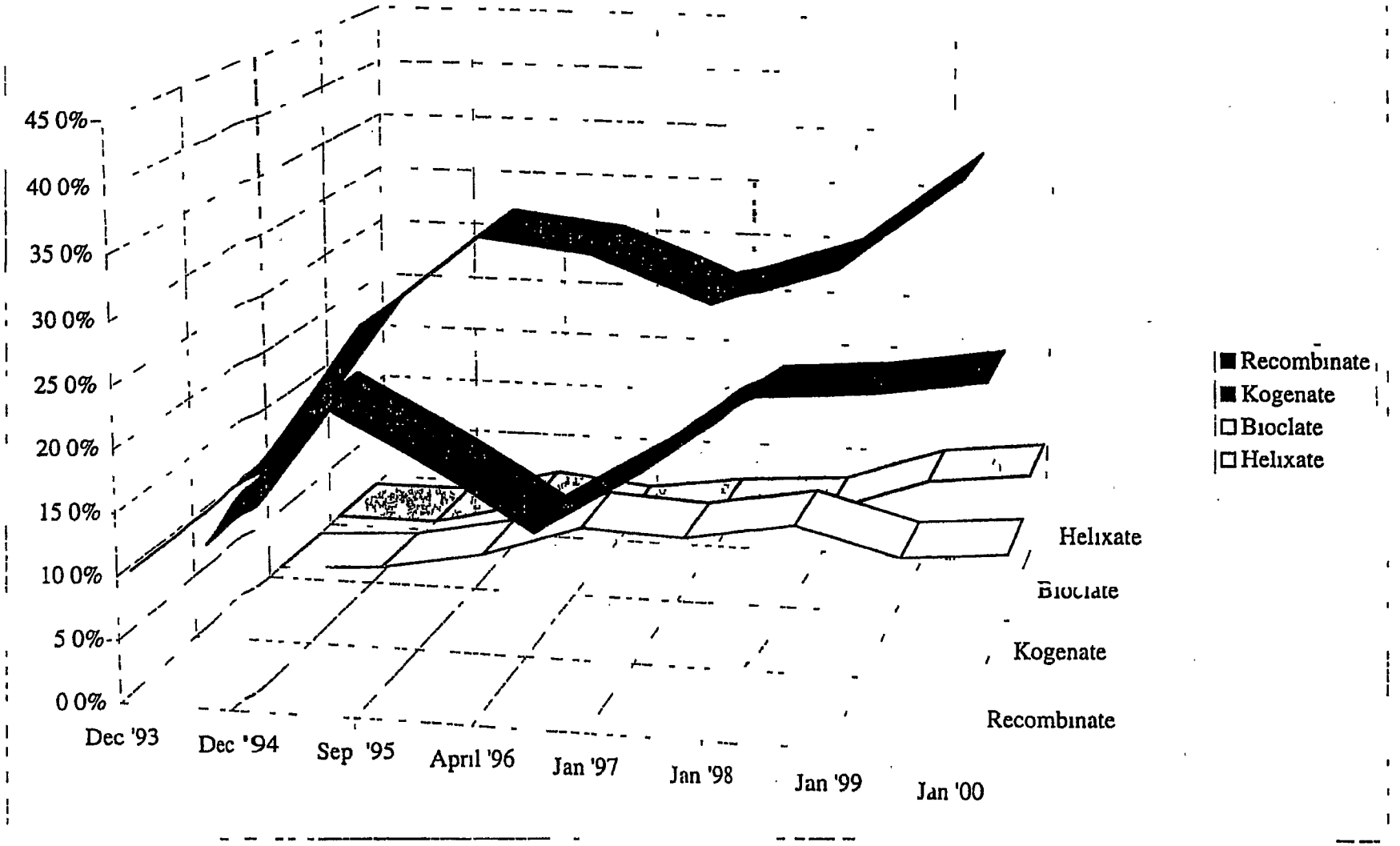

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Table 2

HEMOPHILIA CARE AND PRICE MONITORING

IN THE UNITED STATES WAVE #10 - JANUARY 2000

THE COAGULATION FACTOR CONCENTRATE MARKET - USA - 2000

Percent Distribution of Hemophilia A Patients in Survey Sample by Factor VIII Concentrate - December 1993 to January 2000

	January '00		January '00 vs Jan '99	January 1999	January 1998	January 1997	January 1996	April 1995	September 1994	December 1993
Product	Patients	Percent	Percent	Percent	Percent	Percent	Percent	Percent	Percent	Percent
Recombinate	1,454	42 3%	6 8%	35 5%	32 7%	35 8%	36 8%	29 8%	17 0%	9 6%
Kogenate	809	23 6%	1 3%	22 2%	21.5%	14 8%	9 4%	14 5%	19 3%	6 9%
Bioclate	166	4 8%	0 8%	4 0%	6 3%	4 7%	5 1%	2 2%	0 5%	0 0%
Helixate	245	7 1%	1 0%	6 1%	3 0%	2 4%	1 2%	2 1%	0 0%	0 0%
Monoclate P	93	2 7%	-0 6%	3 3%	6 1%	12 8%	18 2%	18 2%	26 5%	22 9%
Hemofil M	359	10 5%	-2 8%	13 3%	12 9%	16 1%	18 0%	17 5%	21 7%	22 9%
Monarc-M	291	8 5%	-5 9%	14 4%	13 4%	9 8%	6 5%	8 1%	5 5%	26 6%
Koate HP	13	0 4%	-0 1%	0 5%	3 3%	1 9%	3 2%	5 7%	7 8%	8 4%
Alphanate	4	0 1%	-0 6%	0 7%	0 8%	1 8%	1 7%	1 9%	1 7%	NA
Total Factor VIII	3 433	100 0%		100 0%	100 0%	100 1%	100 1%	100 0%	100 0%	100 0%

Table 3

HEMOPHILIA CARE AND PRICE MONITORING

IN THE UNITED STATES WAVE #10 - JANUARY 2000

THE COAGULATION FACTOR CONCENTRATE MARKET - USA - 2000
Percent Distribution of Hemophilia B Patients in Survey Sample by Factor IX Concentrate - December 1993 to January 2000

	January 2000		January '00 vs Jan '99	January 1999	January 1998	January 1997	April 1996	September 1995	December 1994	December 1993
Product	Patients	Percent	Percent	Percent	Percent	Percent	Percent	Percent	Percent	Percent
BeneFIX	902	79 9%	9 5%	70 4%	43 6%	N A	N A	N A	N A	N A
AlphaNine S/D	67	5 9%	-14 3%	20 2%	23 1%	39 0%	53 7%	49 7%	47 1%	38 0%
Mononine	157	13 9%	5 5%	8 5%	20 1%	49 4%	34 4%	37 5%	42 6%	28 1%
Konyne 80	2	0 2%	-0 2%	0 4%	6 4%	8 7%	10 1%	10 1%	8 1%	32 4%
Profilnine SD	0	0 0%	-0 4%	0 4%	6 1%	2 5%	0 8%	2 5%	2 1%	1 4%
Bebulin VH	1	0 1%	0 0%	0 1%	0 6%	0 4%	0 7%	0 2%	0 1%	0 1%
Proplex I	0	0 0%	0 0%	0 0%	0 2%	0 0%	0 3%	0 0%	0 0%	0 0%
Total Factor IX	1,128	100 0%		100 0%	100 0%	100 0%	100 0%	100 0%	100 0%	100 0%

Chart 2

MARKET SHARES OF FACTOR VIII CONCENTRATES
JANUARY 2000 (Percent of Patients in Sample)

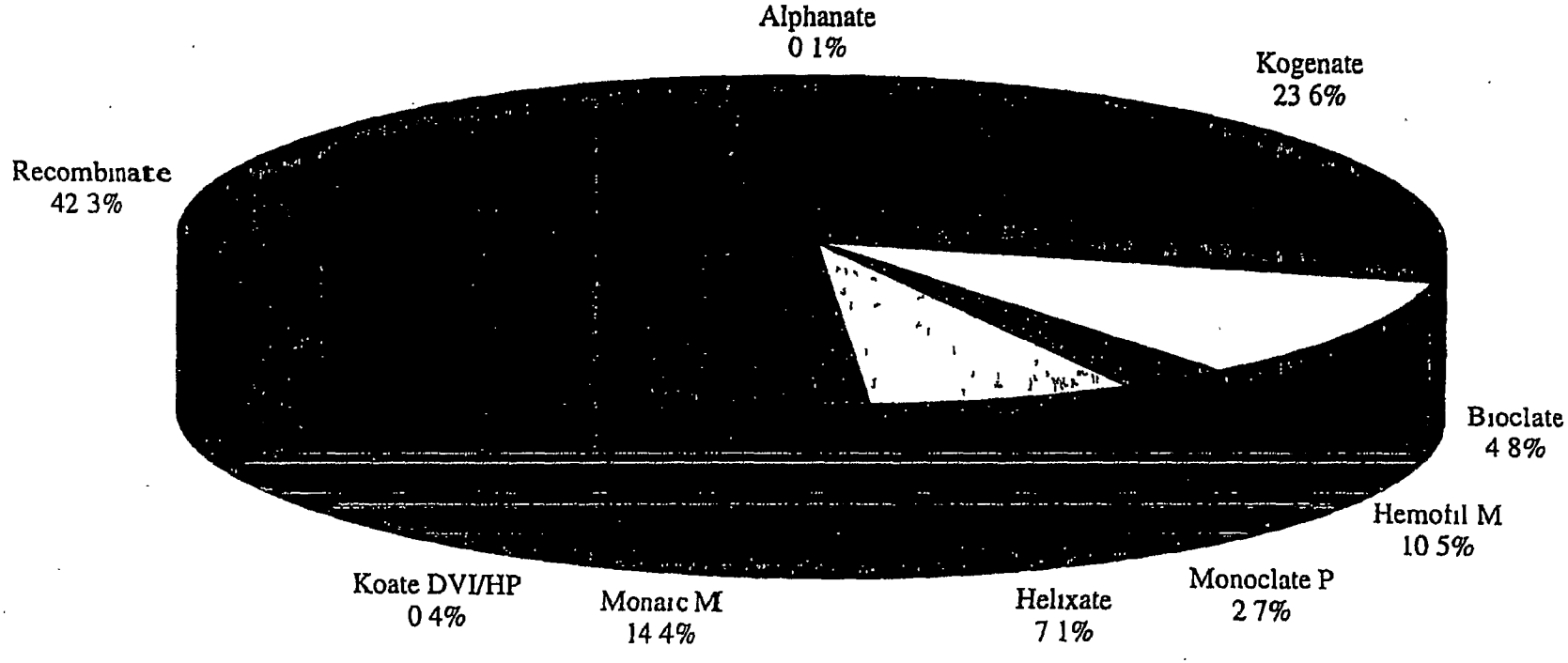

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Chart 3

MARKET SHARE VARIATIONS BETWEEN JANUARY 1999 AND JANUARY 2000 - FACTOR VIII CONCENTRATES
(Percentage of Patients in Sample)

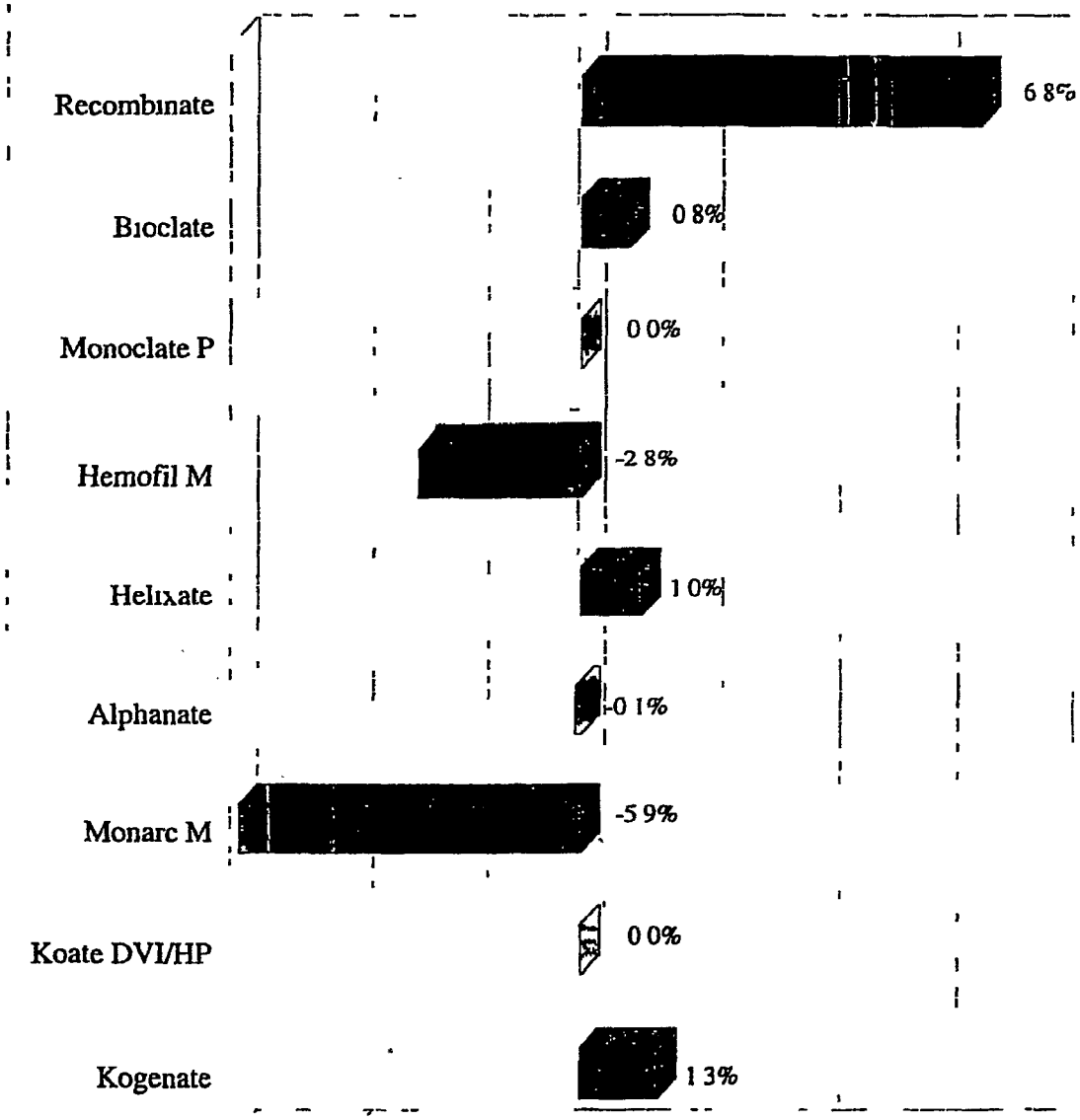
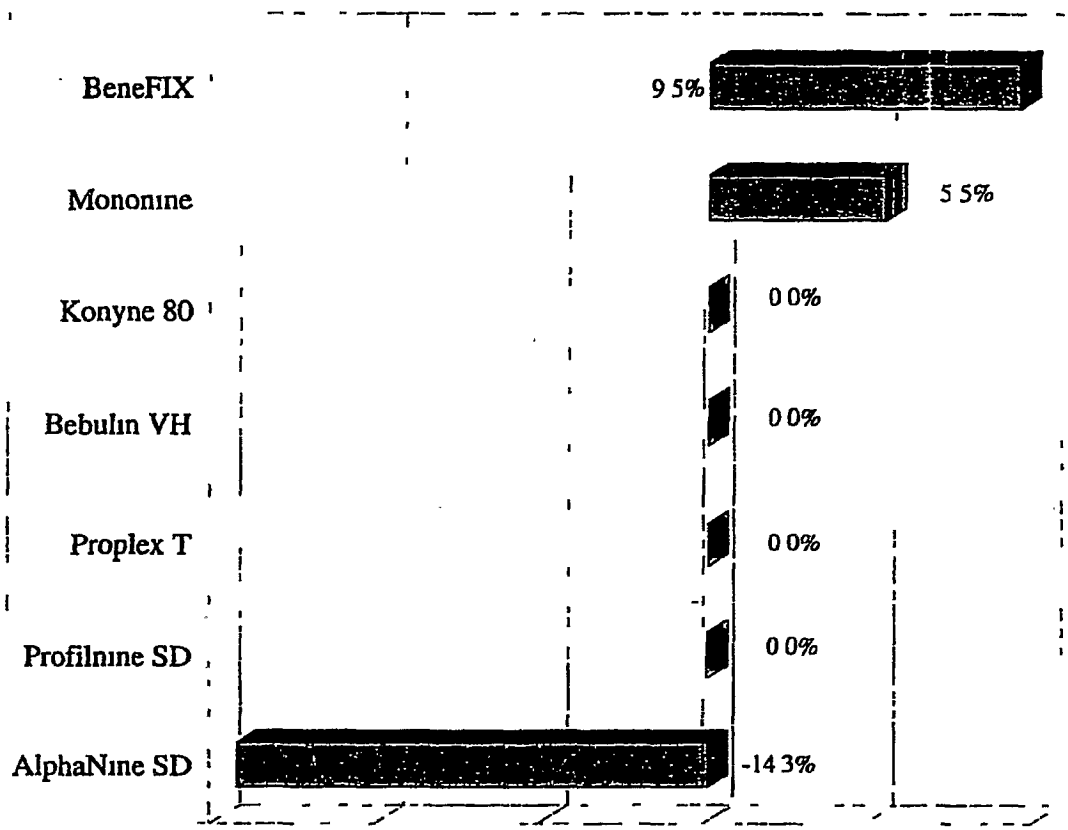


Chart 5

MARKET SHARE GAINS/LOSSES BETWEEN JANUARY 1998 AND JANUARY 2000 - FACTOR IX
(Percentage of Patients in Sample)



3) FACTOR VIII MARKET

According to the survey results, in January 2000, 77 9% of the hemophilia A patients in the sample used a recombinant Factor VIII This represented a 10 percentage point increase from January 1999, which itself had posted an advance of 4 5 percentage points The higher increase in 1999 was attributed to Baxter's increased manufacturing capacity

Among the recombinant Factor VIII concentrates, Recombinate continues to dominate the market with 42 3% of the patients in the sample (+6 8% over January 1999), followed by Kogenate with 23 6% (+1 3%), Helixate (7 1%, +1 0%) and Bioclate (4 8%, 0 8%) Bioclate was expected to be phased out in 1999 but is still available, however with the lowest market share among all the rFVIII products It will be most likely be phased out in 2000, as Baxter is no longer required to manufacture it for Aventis Behring

The progression of the recombinant factor VIII concentrates was at the expense of the monoclonal antibody-purified products which all lost market share

- Hemofil-M lost 2 8 percentage points from 13 3% to 10 5% between January 1999 and 2000,
- Monarc-M lost 5 9 percentage points, from 14 4% to 8.5%,
- Monoclate P went down from 3 3% in January 1999 to 2 7% in January 2000 (-0 6%),
- Koate HP did not move, at close to 0.5%, and
- Alphanate lost 0 6 percentage points, from 0 7% to 0 1%

The progression of recombinant Factor VIII, and the parallel declines of the monoclonal antibody-purified and of intermediate purity Factor VIII concentrates is shown below

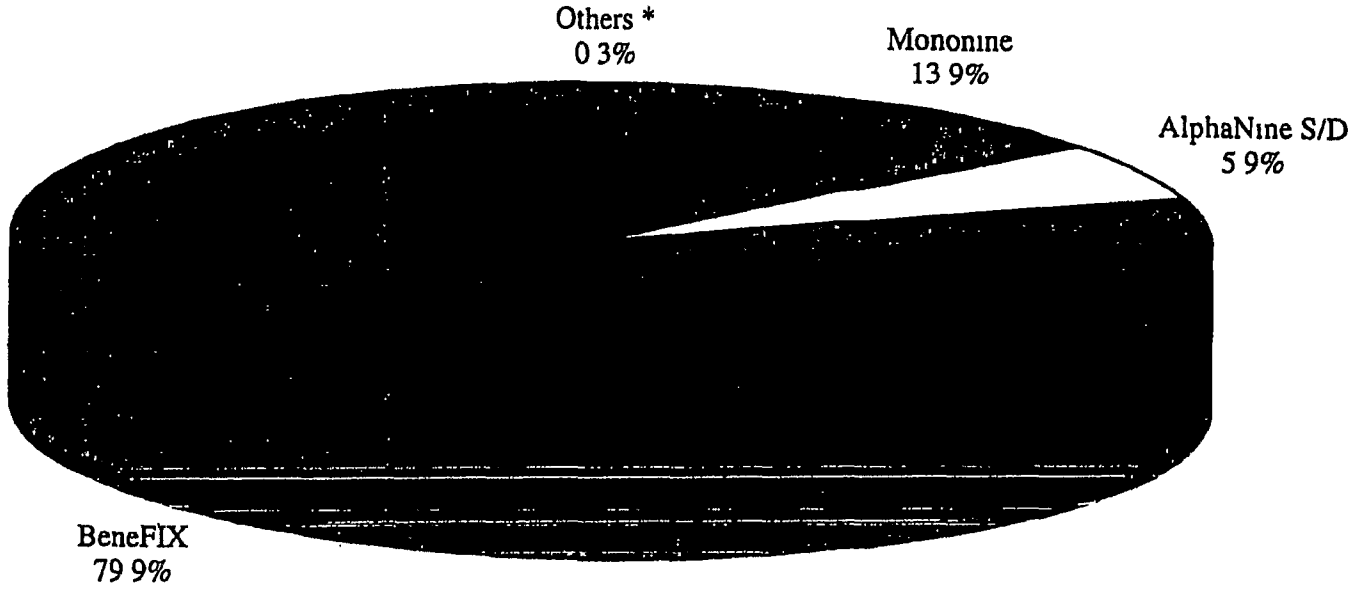
Distribution of Factor VIII Concentrates by Product Category - 1995 to 2000 *

Product	Jan '00	Jan '99	Jan '98	Jan '97	Apr '96	Sep '95
Recombinant	77 8%	67 9%	63 4%	57 6%	53 5%	48 6%
Monoclonal antibody-purified	21 7%	30 9%	32 4%	38 7%	42 7%	43 8%
Intermediate purity	0 5%	1 2%	4 2%	3 7%	4 9%	7 6%
Total	100 0%	100 0%	100 0%	100 0%	100 0%	100 0%

* Percent of patients in the sample

Chart 4

MARKET SHARES OF FACTOR IX CONCENTRATES - JANUARY 2000
(Percent of Patients in Sample)



*** Includes: Bebulin VH, Konyne 80, and Profilinine SD**

3.1) Supply and Demand for recombinant Factor VIII

At the end of 1998, the Factor VIII market was estimated at close to 890 million international units in the United States, and a 7% to 9% increase in volume is expected for 1999, caused by the following factors

- Structure of the patient population the young patients who began using rFVIII in the early 1990's are now teenagers using substantially more product per bleed, per month and per year
- Prophylaxis These patients are not only using more concentrate because of their body size but they are inclined to use product more often and more liberally, for instance before exercising or undertaking some sport activity, or under a secondary prophylaxis regimen,
- Standard Therapy Many physicians who were concerned about the safety profile of rFVIII are now recognizing that it can be prescribed without risk The recombinant Factor VIII concentrates have been used for seven years without causing any major accident For these practitioners, the "wait and see" period is now enough, and they have no more doubt about the safety of rFVIII Even the issue of inhibitor development allegedly caused by recombinant Factor VIII has virtually disappeared, except for a limited number of physicians or nurses who remain unconvinced Recombinant Factor VIII has now become the standard therapy for hemophilia A in the United States
- Immune Tolerance The number of patients on immune tolerance (IT) for the eradication of an inhibitor continues to grow,
- Shortage of some Plasma-derived Factor VIII Concentrates In the past two years the shortage of Monoclate P has forced many patients to switch to another product While a number of them opted for another plasma derived product, such as Hemofil-M or Monarc-M the majority decided to "trade up" to a recombinant product, despite the higher cost,
- Reimbursement The insurance companies are now aware of the advantages and increased safety of recombinant Factor VIII products, and they are more willing to cover their cost
- Lower Pricing The downward pricing trend observed in the past three years or so has facilitated the patients' switch to rFVIII although a counter-trend seems has been observed in 1999

Faced with a growing demand, which also occurred in Europe and Japan where these products gained strong acceptance from 1994 onwards, the two manufacturers had difficulties in maintaining an adequate supply of recombinant Factor VIII Both Baxter and Bayer set up various allocation programs which somewhat limited the supply to their customers while new patients began to use these products, too, contributing to higher demand

Baxter's *Hemofil M* and the American Red Cross' *Monarc-M* were not in short supply in 1999, whereas Bayer's *Koate HP* and Alpha Therapeutic's *Alphanate* also experienced some supply difficulties, while Aventis Behring's *Monoclate P* became largely available only at the end of the year

In 2000, the availability of larger quantities of Baxter Hyland/Immuno's *Recombinate* made at the new plant in Thousand Oaks, California, the approval of Wyeth Ayerst *ReFacto* and possibly of Bayer's *Kogenate* "sucrose formulated", and now called *Kogenate FS* will further relieve the supply situation However, the uncertainty about the Factor VIII assays (two-stage vs chromogenic) is considered a problem in the opinion of a few respondents who are not sure about the practical implications of this new testing methods Wyeth Ayerst is reported to be building a new manufacturing plant in St Louis, in addition to another one in Ireland ReFacto will be manufactured in both these facilities, however not before 2001 or later

Baxter is reported to be working towards the development of a new, albumin-free, full length molecule recombinant Factor VIII

As BeneFIX is completely albumin-free, it has been speculated that its poor recovery might be linked to the absence of albumin However, the clinical trials of ReFacto indicate that its recovery is equivalent to the products currently available

As Monoclate P became available in large quantities at the end of 1999, its market share was not much higher in January 2000 than a year ago This may change in the course of the year, if patients can be convinced to switch back to this product In May 1999, Bayer launched "Koate DVI" (double Virus Inactivated) and recorded a good market acceptance, although the product is more successful in the export markets because of the U S patients' preference for technologically more advanced products, including Kogenate

In 1999, the Average Wholesale Price (AWP) of several products increased (see page 44 below) Furthermore, the actual acquisition prices went slightly up, while the reimbursement prices eroded The fractionators may have tried to compensate for the revenue losses of other plasma products, in particular albumin

Table 4

HEMOPHILIA CARE AND PRICE MONITORING

IN THE UNITED STATES WAVE #10 - JANUARY 2000

THE COAGULATION FACTOR CONCENTRATE MARKET - USA - 2000

ACQUISITION PRICES OF FACTOR CONCENTRATES - JANUARY 2000

Product	January 2000 Acquisition Prices (per IU)				January '00 vs Jan '99	January 1999	January 1998	April 1997	September 1996	December 1995	December 1994	December 1993
	Average	Maximum	Minimum	Spread								
Bioclate	0 67	0 80	0 51	0 29	0 01	0 65	0 63	0 67	0 66	0 64	0 76	NA
Helixate	0 65	0 80	0 48	0 32	0 04	0 61	0 61	0 67	0 66	0 65	0 76	NA
Kogenate	0 70	0 80	0 55	0 25	0 04	0 66	0 64	0 66	0 66	0 67	0 71	0 75
Recombinate	0 70	0 88	0 62	0 26	0 06	0 64	0 64	0 65	0 68	0 68	0 76	0 82
Alphanate	0 39	0 50	0 29	0 21	0 04	0 36	0 34	0 32	0 32	0 32	0 32	NA
Hemofil M	0 47	0 69	0 36	0 33	0 03	0 43	0 41	0 48	0 49	0 50	0 61	0 60
Koate DVI/HP	0 43	0 77	0 36	0 41	0 13	0 29	0 25	0 25	0 22	0 23	0 28	0 27
Monarc - M	0 34	0 41	0 27	0 14	0 02	0 32	0 33	0 36	0 36	0 38	0 42	0 39
Monoclate P	0 51	0 60	0 41	0 19	0 02	0 49	0 50	0 57	0 55	0 58	0 65	0 58
BeneFIX	0 73	0 88	0 66	0 22	0 03	0 71	0 71	NA	NA	NA	NA	NA
AlphaNine SD	0 47	0 75	0 42	0 33	0 07	0 54	0 55	0 55	0 52	0 56	0 59	0 63
Mononine	0 68	0 83	0 61	0 22	0 02	0 66	0 69	0 71	0 69	0 69	0 73	0 76
Konyne 80	0 15	0 32	0 09	0 23	0 02	0 14	0 14	0 13	0 13	0 13	0 15	0 15
Profilnine SD	0 29	0 35	0 13	0 22	0 11	0 18	0 17	0 19	0 19	0 15	0 13	0 17
Proplex I	0 19	0 25	0 17	0 08	0 03	0 16	0 14	0 15	0 15	0 15	0 16	-
Bebulin VII	0 26	0 30	0 10	0 20	0 03	0 23	0 22	0 26	0 26	0 25	0 33	-
Feiba VH	0 81	0 90	0 73	0 17	0 05	0 76	0 75	0 78	0 78	0 81	0 77	0 85
Autoplex I	0 74	0 93	0 63	0 30	0 05	0 69	0 69	0 86	0 75	0 76	0 85	0 86
Hyate C	1 59	1 83	1 29	0 54	0 21	1 38	1 25	1 33	1 36	1 40	1 15	1 19
NovoSeven	0 75	0 97	0 67	0 30	NA	NA	NA	NA	NA	NA	NA	NA
Humate P	0 67	0 96	0 57	0 39	0 17	0 84	0 87	0 95	0 85	0 95	1 04	0 93

Chart 6

ACQUISITION PRICES OF FACTOR VIII CONCENTRATES
JANUARY 1997 TO JANUARY 2000
(Dollars per International Unit)

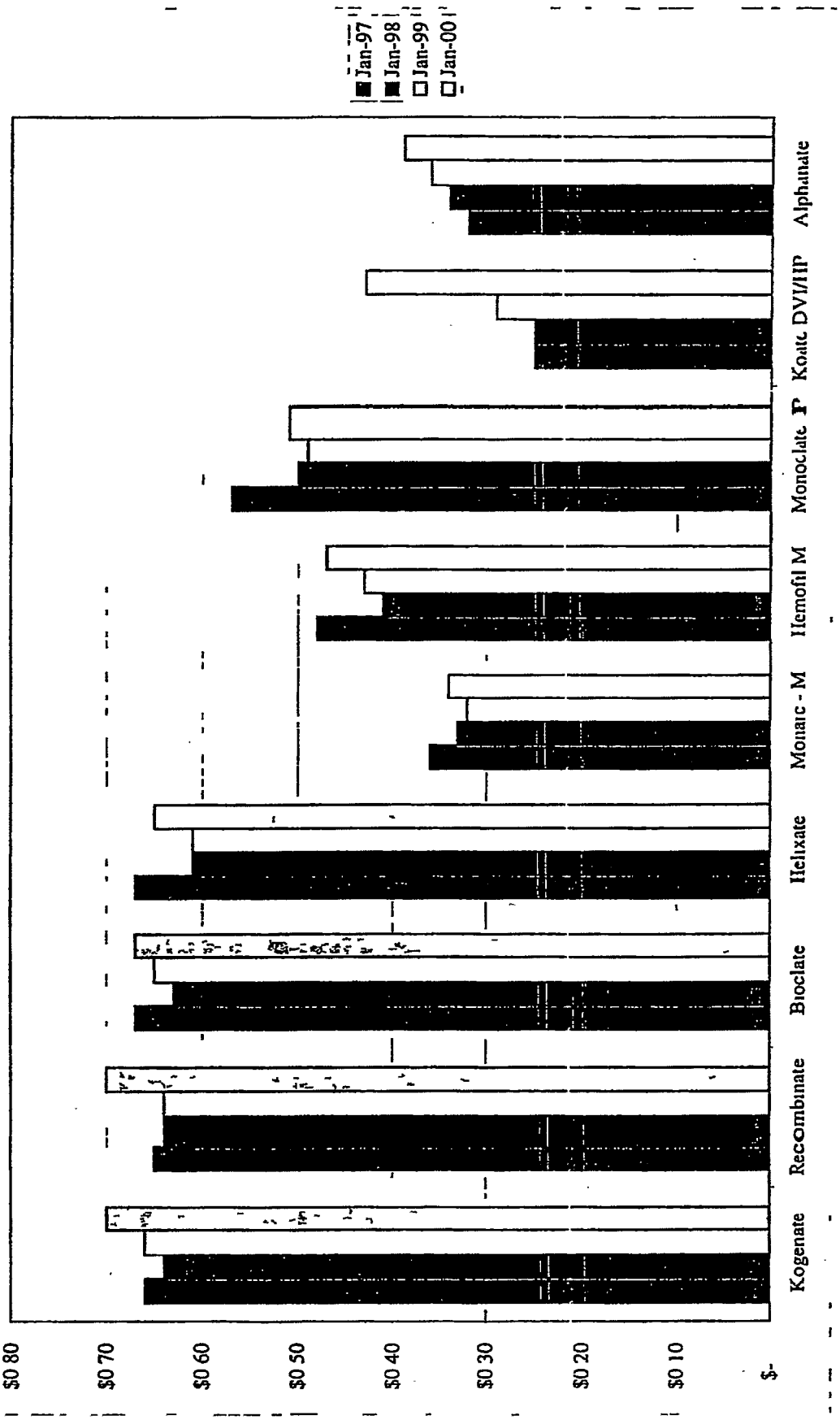


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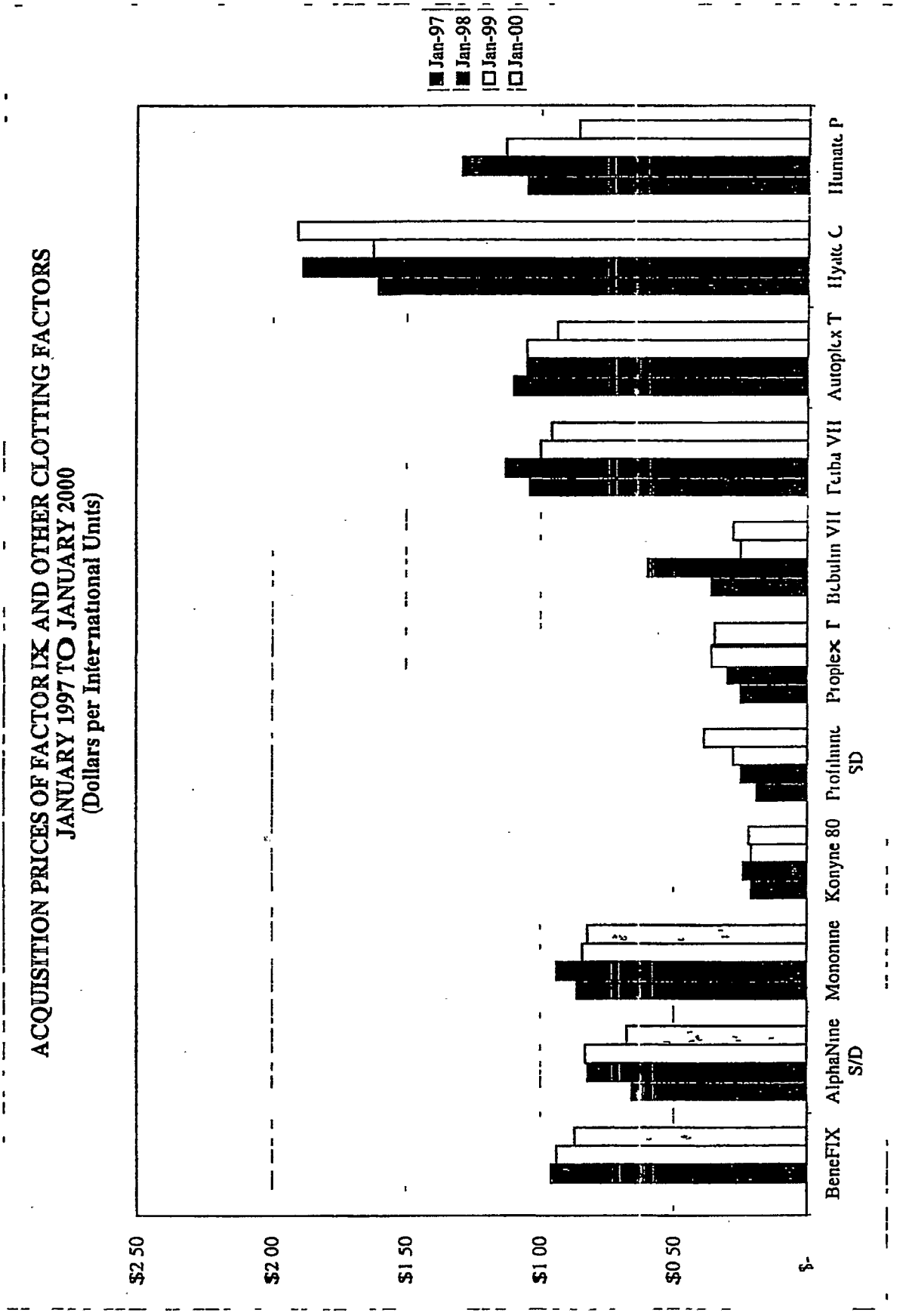
Chart 7

ACQUISITION PRICES OF FACTOR IX AND OTHER CLOTTING FACTORS
JANUARY 1997 TO JANUARY 2000
(Dollars per International Units)



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3 2) Pricing Trends

In January 2000, the average acquisition price of recombinant Facto VIII was close to $0 70 per international unit, an increase of about five US cents over January 1998 Both Kogenate and Recombinate averaged 70¢ per unit, while Bioclate and Helixate averaged about 66¢ per unit. Monoclate P's price was 51¢ and Hemofil M's, 47¢ per unit The difference between the plasma-derived product and the recombinant remains in the neighborhood of twenty cents per unit It is even higher when considering Monarc M, whose price was recorded at 34¢ per unit This suggests that price is not a critical obstacle today when choosing between a plasma-derived and a recombinant Factor VIII concentrate, including for patients on primary prophylaxis or immune tolerance

Overall, between January 1999 and January 2000, the acquisition prices of the various concentrates posted slight increases, the highest being for Koate DVI which was different from Koate HP therefore more expensive, and for Profilnine (+11¢) An increase in the price of Hyate C (+21¢) was also noted On the other hand the price per unit of Humate P went down because of a difference in the pricing method whereby the price is based on the "ristecin cofactor" activity, and not Factor VIII C activity

Price Changes between January 1999 and January 2000 by Product Category

Product	Acquisition Price	Patients Price
- Recombinant Factor VIII	±5¢ per Unit	-6¢ per Unit
- Monoclonal Antibody-purified Factor VIII	±2¢ per Unit	-10¢ per Unit
- Intermediate Purity Factor VIII	+4 to +13¢ per Unit	+3 to +9¢ per Unit
- Recombinant Factor IX	+3¢ per Unit	-7¢ per Unit
- "Pure" Factor IX	-7 to +2¢ per Unit	-2 to -15¢ per Unit
- Factor IX Complex Concentrates	-3 to +11¢ per Unit	-1 to + 12¢ per Unit
- Activated Factor IX Complex Concentrates	+5¢ per Unit	-4 to -11¢ per Unit

The downward pricing trend which began five years ago, when the "VA Bill" was introduced, seems to have taken a reversal Today, some 45 treatment centers apply the provision of this bill, approximately the same number as last year Some manufacturers have taken steps to keep their prices at a "reasonable" level, by managing their "lowest price accounts" more carefully

Contrary to the acquisition prices, the patient prices experienced a downward tendency in the past twelve months the recombinant Factor VIII concentrates lost about 6¢ to average $0 82 per international unit The monoclonal antibody-purified products ranged from $0 45 for Monarc-M

(-4¢) to $0 75 for Monoclate P, with $0 63 for Hemofil-M (-9¢) These prices represent primarily those paid by patients treated at HTCs They differ from the reimbursement prices billed by home care companies to insurance firms which are based on the AWP, which increased for several products in 1999

4) FACTOR IX MARKET

4.1) BeneFIX vs Mononine

In January 2000, BeneFIX and Mononine together were used by 94% of all hemophilia B patients in the sample (1,128 hemophilia B patients) 79 8% of them used Genetics Institute's *BeneFIX* a gain of 9 5 percentage points over January 1999 No shortage of this product was experienced and the only issue mentioned about the product was its low recovery, generally considered as a minor inconvenience by the respondents Although this contributed to increasing the treatment expenditure, its higher cost was seldom mentioned, showing that the cost is no longer a major problem For its part, Mononine posted a substantial market advance (+5 5%), thanks to increased availability, and reached 13 9% market share The price per Unit of BeneFIX and Mononine are comparable ($0 87 and $0 82 respectively) but the need to infuse more of the former makes Mononine less expensive per bleed Aventis Behring was therefore successful in regaining some of its patients lost to BeneFIX, and, more likely, in attracting patients who were unable to obtain AlphaNine SD The Factor IX market displayed the following trends

- AlphaNine SD which was in short supply through 1999, lost 14 3 percentage points between January 1999 and January 2000, and its market share went down from 20 2% to 5 9%
- Mononine gained 5 5 percentage points, and reached almost 14% share as opposed to 8.5% last January,
- The combined share of Konyne 80, Profilnine, Bebulin VH, and Proplex T went from near 14% in January 1998 to 0 9% in January 1999, and less than 0 4% in January 2000 PCCs are virtually no longer used in the U S , partially due to unavailability

Table 5

HEMOPHILIA CARE AND PRICE MONITORING

IN THE UNITED STATES WAVE #10 - JANUARY 2000

THE COAGULATION FACTOR CONCENTRATE MARKET - USA - 2000

PATIENT PRICES OF FACTOR CONCENTRATES - JANUARY 2000

Product	January 2000 Acquisition Prices (per IU)				January '00	January	January	April	September	December	December	December
	Average	Max	Min	Spread	vs Jan '99	1999	1998	1997	1996	1995	1994	1993
Bioclate	0 82	1 00	0 74	0 26	-0 07	0 88	0 86	0 88	1 07	0 84	1 09	NA
Helixate	0 83	0 94	0 74	0 20	-0 05	0 88	0 86	0 81	1 00	0 89	1 20	NA
Kogenate	0 82	1 00	0 74	0 26	0 05	0 86	0 93	0 84	1 00	0 95	1 03	0 99
Recombinate	0 83	1 00	0 74	0 26	-0 04	0 87	0 91	0 88	1 05	0 94	1 03	1 10
Alphanate	0 58	0 80	0 48	0 32	0 03	0 55	0 54	0 46	0 59	0 59	0 50	NA
Hemofil M	0 63	0 95	0 51	0 44	-0 09	0 72	0 74	0 59	0 72	0 66	0 89	0 77
Koate HP	0 52	0 80	0 26	0 54	0 09	0 43	0 40	0 35	0 50	0 38	0 53	0 40
Monarc - M	0 45	0 49	0 40	0 09	0 03	0 49	0 58	0 46	0 79	0 80	0 78	0 57
Monoclate P	0 75	1 00	0 65	0 35	0 11	0 86	0 84	0 78	0 83	0 79	0 94	0 74
BeneFIX	0 87	1 25	0 77	0 48	0 07	0 94	0 96	NA	NA	NA	NA	NA
AlphaNine SD	0 67	0 95	0 62	0 33	0 15	0 83	0 82	0 65	0 91	0 78	0 97	0 85
Mononine	0 82	1 00	0 78	0 22	0 02	0 84	0 94	0 86	0 97	0 93	1 04	0 88
Bebulin VH	0 28	NA	NA	NA	0 03	0 25	0 60	0 36	0 50	0 53	0 53	0 28
Konyne 80	0 22	0 31	0 20	0 11	0 01	0 21	0 24	0 21	0 28	0 32	0 26	0 20
Profilnine SD	0 39	0 40	0 38	0 02	0 12	0 28	0 25	0 19	0 30	0 25	0 28	0 19
Proplex T	0 35	NA	NA	NA	-0 01	0 36	0 30	0 25	0 29	0 60	0 43	NA
Feiba VH	0 96	1 12	0 91	0 21	0 04	1 00	1 13	1 04	1 19	1 09	1 29	1 12
Autoplex T	0 94	1 20	0 86	0 34	-0 11	1 05	1 05	1 10	1 22	0 96	1 18	0 78
Hyate C	1 91	2 03	1 81	0 22	0 28	1 63	1 89	1 61	1 89	1 90	1 45	1 34
NovoSeven	0 90	1 30	0 79	0 51	NA	NA	NA	NA	NA	NA	NA	NA
Humate P	0 86	1 50	0 65	0 85	0 27	1 13	1 30	1 05	1 26	1 27	1 32	1 48

Chart 8

PATIENT PRICE OF FACTOR VIII CONCENTRATES
JANUARY 1997 TO JANUARY 2000
(Dollars per International Unit)

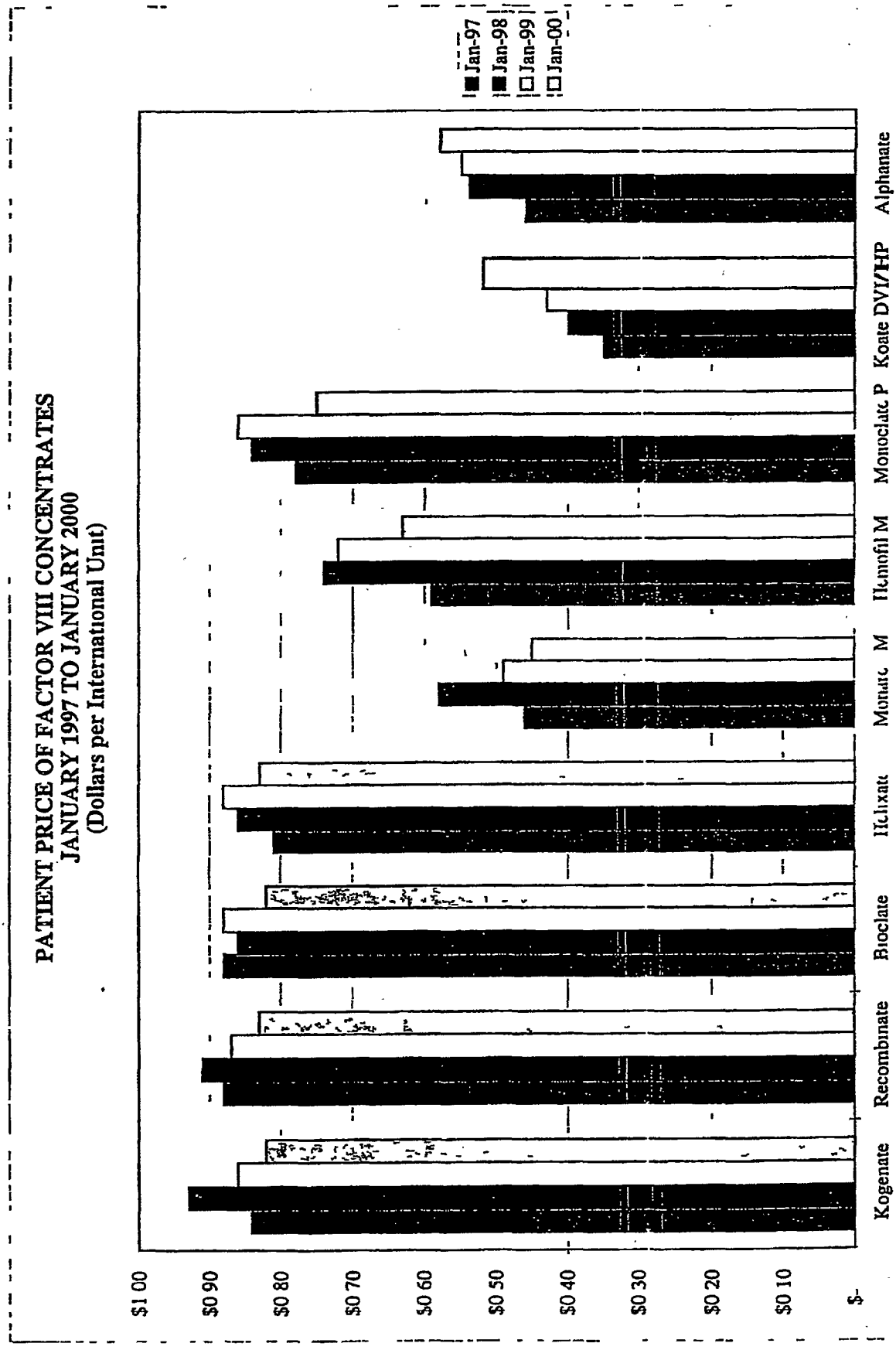

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Chart 9

PATIENT PRICE OF FACTOR IX AND OTHER CLOTTING FACTORS
JANUARY 1997 TO JANUARY 2000
(Dollars per International Unit)

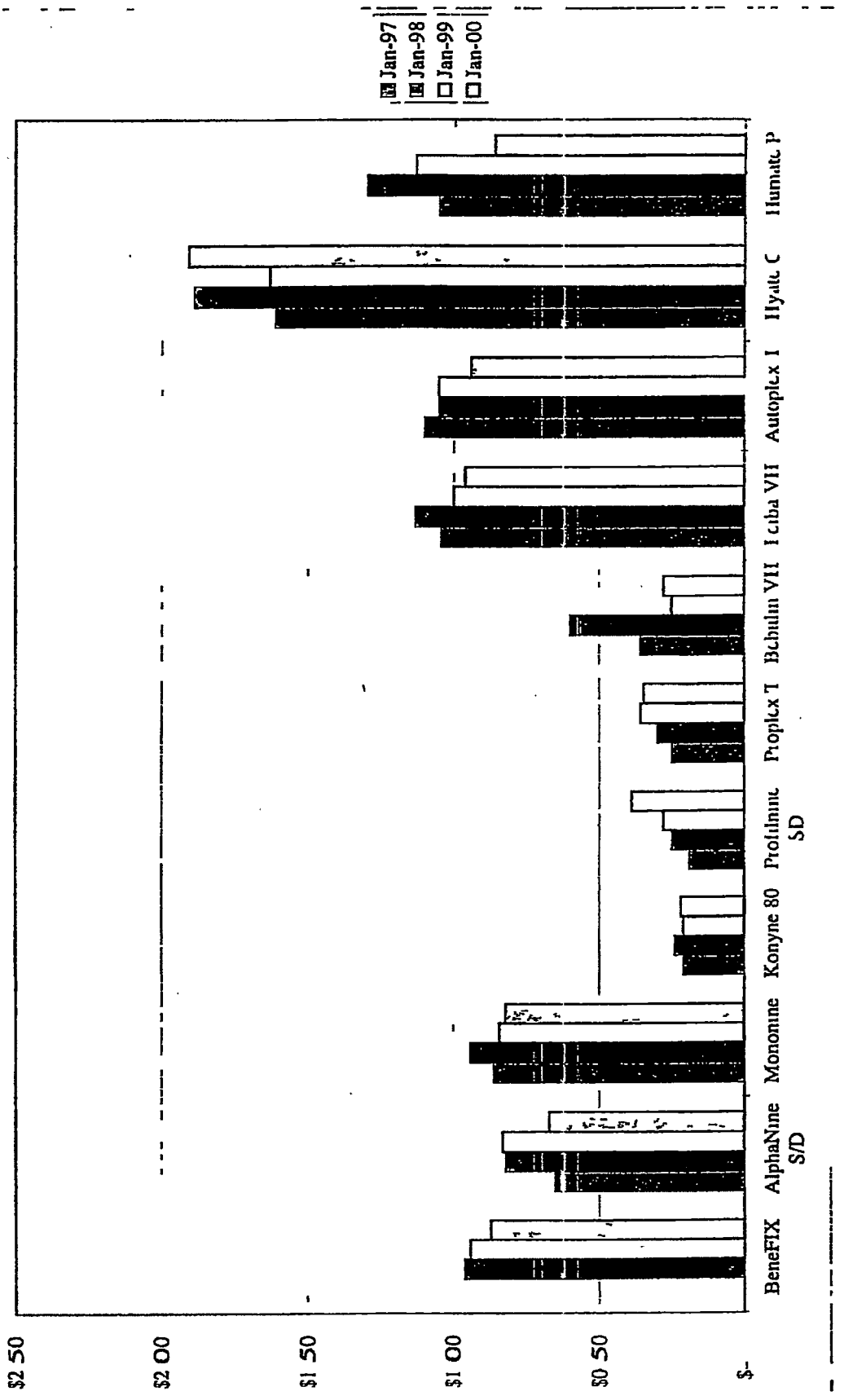

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Table 6

HEMOPHILIA CARE AND PRICE MONITORING

IN THE UNITED STATES WAVE #10 - JANUARY 2000

FACTOR CONCENTRATES PRICE CHANGES BETWEEN 1993 AND 2000		
Product	Acquisition Prices	Patient Price
Kogenate	-6.5%	-7 7%
Recombinate	-14 8%	-24 3%
Hemofil M	-22 4%	-18 3%
Koate DVI/HP	58 9%	30 0%
Monarc - M	-12 0%	-20 5%
Monoclate P	-12 4%	1 5%
AlphaNine SD	-25 2%	-21 0%
Mononine	-10 1%	-6 6%
Bebulin VH	-22 2%	0 0%
Konyne 80	0 7%	9 2%
Profilnine SD	72 0%	105 3%
Feiba VH	-4 9%	-14 6%
Autoplex T	-14 0%	20 7%
Hyate C	33.5%	42 3%
NovoSeven	N A.	N.A.
Humate P	-27 9%	-42 1%

BeneFIX was introduced in Europe in April 1999, and enjoyed a good initial acceptance level. However, it competes against a myriad of plasma-derived Factor IX concentrates including those manufactured by the very company which distributes BeneFIX in Europe (Baxter)

The progression of recombinant Factor IX, and the parallel decline of the "pure" Factor IX and of the Prothrombin Complex Concentrates (PCC, also called "Factor IX Complex") is shown below

Distribution of Factor IX Concentrates by Product Category - 1995 to 2000

Product	Jan '00	Jan '99	Jan '98	Jan '97	Apr '96	Sep 95
Recombinant	79 9%	70 4%	43 6%	N.A.	N.A	N.A.
"Pure" Factor IX	19 8%	28 7%	43 2%	88 4%	88 1%	87 7%
Factor IX Complex	0 3%	0 9%	13 2%	11 6%	11 9%	12 3%
Total	100 0%	100 0%	100 0%	100 0%	100 0%	100 0%

(Percent of patients in the sample)

4 2) The fading Role of Prothrombin Complex Concentrates (PCC)

The unavailability of the Prothrombin Complex concentrates, Konyne 80 and Profilnine SD which suffered production problems in 1999 contributed to the overall demise of this kind of product in particular in the treatment of hemophilia B

These products which are also known as "Factor IX Complex Concentrates" have four main indications, and the breakdown of use for each one is not available

- Replacement therapy for Factor IX-deficient patients These products are used in mild hemophilia B patients for whom the thrombolytic risk is limited, as they use a comparatively small quantity of product Some of these patients may also have financial constraints and may use a PCC because it is the least expensive among all the clotting factors on the market The number of such patients has probably been further reduced by the shortage of Konyne 80 and Profilnine SD, and they may have switched to either Mononine BeneFIX or possibly AlphaNine SD

- Treatment of hemophilia A patients with inhibitors Although this approach has now almost disappeared in the U S , some Hemophilia Treatment Centers used to correct a bleed in a hemophilia A patient with inhibitor with *Konyne 80, Profilnine SD*, or less frequently Baxter's *Bebulin VH* before they use an another anti-inhibitor Complex Concentrate (AICC) such as an

activated Factor IX Complex Concentrate (*Autoplex T* or *Feiba VH*) or another product such as porcine Factor VIII (Speywood's *Hyate C*) or recombinant Factor VII a (Novo Nordisk's *NovoSeven*) If Konyne 80 or Profilnine SD was effective, then the patient has the added benefit of a relatively inexpensive treatment PCCs are also prescribed to patients who developed acquired hemophilia A during surgery associated with an inhibitor, although Hyate C is currently the product of choice in this indication

- Treatment of Factor X and Factor VII deficiencies A few individuals suffer from Factor II, Factor VII or Factor X deficiency PCCs contain these factors, and may be used to correct these deficiencies when there is a bleed Baxter's *Proplex T* is known to have a higher content of Factor X than the other PCCs An alternative treatment consists in using fresh frozen plasma (FFP) The market for this indication is rather small, as the number of patients in estimated to be less than a hundred

- Coumadin reversal in surgery patients In this indication, PCC is administered in order to counterbalance the anticoagulation effect of heparin or Coumadin which may lead to excessive bleeding This is reportedly an important market in some Western European countries (Austria, Germany) but its size is unknown in the United States because here is no product specifically indicated for this condition

Between September 1995 and January 1998, the market share of Factor IX Complex Concentrates remained in the 11 to 13% range The sudden drop in 1998 was caused by the shortage of PCCs and, to some extent, the introduction of recombinant Factor IX

4 3) Pricing Trends

Similar to Factor VIII concentrates, the acquisition prices of the Factor IX concentrates went slightly up in the past twelve months, except for three products AlphaNine SD (-7¢), Bebulin VH (-13¢), and Konyne 80 (-3¢) The other products increased by about three U S cents, except Profilnine SD which increased by 11¢ BeneFIX increased by three cents The price difference between the recombinant Factor IX and the "pure" Factor IX concentrates was only five cents per unit, but, as mentioned, more BeneFIX is needed to accomplish the same therapeutic effect as Mononine or AlphaNine SD When this is taken into account, there is a higher difference in the cost of therapy than the price difference among the products would suggest

As regards the reimbursement prices, the patient's prices were generally lower in January 2000 than a year ago, except for Profilnine SD (12¢) The price to the patients of BeneFIX went down by seven cents, and the price of Mononine was down by ten cents

5) VON WILLEBRAND'S DISEASE MARKET

Between January 1999 and January 2000, the number of von Willebrand's Disease patients vWD registered at the Hemophilia Treatment Centers appeared to have increased, partially as a result of the NHF's effort to encourage the identification, diagnosis and treatment of these patients 1,621 patients were recorded in the survey sample, 4 9% of whom were Type IIb, and 2.4% Type III

The approval of Aventis Behring's *Humate P* for the treatment of vWD and its increased supply represented a significant improvement from the dire situation of 1998 when surgeries had to be postponed, and cryoprecipitate was used at some centers, in lieu of Humate P In 1999 Aventis Therapeutic's *Alphanate* shortage led a few vWD patients to use Koate DVI This was a change from earlier years, when Koate HP was considered inappropriate, or lacking efficacy in the treatment of von Willebrand's disease

The mild patients (type I) who represent the bulk of the vWD patient population (over 80% were able to control their occasional bleeds with DDAVP and/or Stimate, in most instances using the nasal spray. The cost of the IV formulation was reported in the $380-$400 range per dose

According to the survey data, only 7 6% of the vWD patients (123/1,621) were infusing a Factor VIII on a regular basis Humate P was used by 5 4% of them (+2 9 percentage points) Alphanate by 1 2% (-0 8%), and Koate DVI, by 1 0% This did not include the infusion of concentrates in surgery which constitutes probably the bulk of clotting Factor usage among vWD patients

Breakdown of von Willebrand's Disease Patients

Product	Percentage of Patients in the Sample (January 1999)
DDAVP/Stimate	92 4%
Humate P	5 4%
Alphanate	1 2%
Koate DVI/HP	1 0%
Total	100 0%

It is generally agreed that Alphanate is easier to infuse, due to the smaller volume required Furthermore, the treatment with Alphanate is less expensive than with Humate P even though the company reduced the price of Humate P

The American Red Cross has been conducting the clinical trials of a vWD concentrate manufactured by the French Laboratory for Plasma Fractionation (LFB) for several years This trial is reportedly under review

Price Changes between January 1999 and January 2000
(Dollars/Cents per International Unit)

	Price in January 2000		Change 2000 vs 1999	
Product	Acquisition Price	Patients Price	Acquisition Price	Patients Price
- Humate P	$0 67	$0 86	-17¢	-27¢
- Alphanate	$0 39	$0 58	-4¢	+3¢
- Koate DVI	$0 43	$0 52	+13¢	+9¢

The above figure show that that there is still a substantial price difference between Alphanate, Koate DVI on the one hand, and Humate P on the other, about 28¢ at Patient price level, even though the price per unit of Humate P went down in the past twelve months

Table 7 **HEMOPHILIA CARE AND PRICE MONITORING**

IN THE UNITED STATES WAVE #10 - JANUARY 2000

Mode of Treatments for Hemophilia Patients with Inhibitors -January 2000

Inhibitors	Treatment	Patients	Percent
Low Responders	Mass Dose	178	
High Responders	Immune Tol	74	30%
	PCC	0	0%
	Feiba VH	92	38%
	Autoplex T	27	11%
	Hyate C	1	0%
	Novoseven	50	20%
	Sub-Total	244	100%
Low + High resp	Total	422	

6) THE MARKET FOR HEMOPHILIA PATIENTS WITH INHIBITORS

Patients with an inhibitors to Factor VIII or IX are either "high responders" when their inhibitor level, measured in "Bethesda Units" per ml or plasma, exceeds ten or "low responders" when their level is lower than ten BUs This terminology stems from the patient's reaction to an infusion of clotting factor The "high responder" patient is an individual who has a large quantity of antibodies to Factor VIII or IX which generate a strong "response" to an infusion of clotting Factor, by "inactivating" it In other words, the "high responder" continues to bleed even after an infusion of clotting factor, which has virtually lost its efficacy Clotting factors are somewhat efficacious in the "low responders" who can often be treated with large amounts of clotting factor In such a situation, the treatment attempts to overwhelm the antibodies with a large quantity of clotting factors A somewhat similar principle is applied in the protocols inducing "immune tolerance" (IT), whereby the patient's body is gradually familiarized with Factor VIII or IX so that, after a few weeks or months, his body "accepts", or "tolerates" the infusions of factor VIII or IX. When this happens, the patient is "tolerized"

Immune tolerance induction requires a strong commitment on the part of the patient and his family It also requires a large volume of clotting factor, as the patient is infused once a day at a regimen of about 80 to 100 IUs per kilogram of bodyweight Immune tolerance does not seem to work with hemophilia B patients, for reasons not well understood Patients on IT occasionally need infusion of an Anti Inhibitor Complex Concentrates (AICC) product (also called aPCC) to control a sudden bleed

Once the patient is tolerized, however, it is generally for life, as it is estimated that only 25% of them get an inhibitor back The risks of bleeds which cannot be controlled by infusions on demand of Factor VIII or IX in these patients is therefore eliminated for good, and they do not have to resort to complicated and possibly more expensive therapies involving Anti Inhibitor Complex Concentrates (AICC) products or other procedures, such as IGIV, etc Cobe is reported planning to introduce the inhibitor treatment developed in Sweden by Excorim involving plasmapheresis and cleansing of the patient's plasma

422 patients with an inhibitor to Factor VIII or IX were recorded in the sample, or 9 3% of the total (422/4,561) Some 42% of them were estimated to be low responders, 58% high responders who were treated with immune tolerance or an AICC The treatment is not as clear-cut as in the case of hemophilia because inhibitor patients react differently to different products An inhibitor patient may be on IT but may also require infusion of an aPCC, or he may change product, etc

Therefore, the figures below must be treated with caution, as they only represent a "best guess" estimate, as far as market shares are concerned Approximately 30% of the high responders were prescribed an immune tolerance regimen, some 38% used Feiba VH to control their bleeds and 11% used Autoplex T These percentages did not differ significantly from the previous year However, there was a large difference with respect to the way the remaining 21% patients (among high responders only) were treated instead of using a PCC (Konyne 80 or Profilnine SD) nearly almost all used NovoSeven, Hyate C remaining a last resort therapy for a small number of patients who did not respond to the other products This is not to say that there was a direct shift from PCC to NovoSeven, but rather that some of the patients who were treated with a Prothrombin Complex Concentrate switched to Autoplex T or Feiba VH, and some patients who were using Autoplex T or Feiba VH switched to NovoSeven This situation was largely attributed to the unavailability of both Profilnine SD and Konyne 80 through 1999 A small number of patients were treated with Bebulin VH At the beginning of 2000, both Konyne 80 and Profilnine SD became somewhat available again and apparently regained some of their market share although this was not reflected quantitatively in the survey results, as it was fielded in the first two months of 2000

Breakdown of Treatments for Inhibitor Patients
(High and Low Responders combined)

	Percentage of Patients in the Sample	
Product	(January 2000)	(January 1999)
Immune Tolerance	30 3%	30 6%
Feiba VH	37 7%	40 3%
Prothrombin Complex Concentrate	0 2%	17 9%
Autoplex T	11 1%	9 2%
Hyate-C	0 3%	1 0%
NovoSeven	20 4%	1 0%
Total	100 0%	100 0%

In the last twelve months, immune tolerance (IT) induction has not increased significantly possibly because the patients/parents' levels of interest and compliance are slow to change In the long run however, immune tolerance is expected to progress as an efficient procedure used to eradicate inhibitors in hemophilia patients Better infusion technology (pumps) may also facilitate the application of the protocol Furthermore, the financial aspects of the procedure may become easier if the prices of clotting factors decline, as they have in recent years Finally, a better knowledge and recognition of the long term benefits of IT may convince more and more parents to choose it Reportedly, IT is routinely offered as the first option to the parents of a young hemophiliac who displays an inhibitor However, the percentage of parents who adopt it remains relatively constant

So far, the relatively growing level of interest, if not acceptance, of IT has not had any significant impact on the sales of either Autoplex T or Feiba VH, which both posted modest increases in sales in 1999 from 1998 The absence of Prothrombin Complex Concentrates (Konyne 80 and Profilnine SD in 1999) did not benefit either products in any significant way because, from a global standpoint, NovoSeven took over the market share of the PCCs

The patients undergoing an immune tolerance induction regimen may register with the National Immune Tolerance Registry at New York Hospital which monitors the number of patient undergoing this procedure, together with other institutions in other countries (Rome, Malmø, etc)

As the number of patients on immune tolerance grows, the use of AICCs may gradually decline However, immune tolerance will never completely replace these products because they are always needed in emergency situations, surgery, and for those patients who fail the IT protocol Furthermore, as mentioned, IT does not seem to be efficacious for hemophilia B patients

Speywood's *Hyate C* was in short supply in 1997, due to manufacturing problems In 1998, the product became available again in limited quantities, and could only be prescribed for "limb and life-saving situations" Upon its reintroduction at the end of 1998, the AWP of Hyate C went up to $2 20 per unit One of the reasons for the price increase was reportedly that many of the pigs used for product manufacturing were found to be inadequate, the donor selection became more stringent and the product became more costly to manufacture In 1999, Hyate C was available at a quasi normal volume level

The approval of NovoSeven in April 1999 ended a long waiting period with the FDA The product was very successful upon its introduction, with sales amounting to an estimated $30 to $35 million in 1999 Survey respondents were all positive about the product although its short half life was reported to make it difficult to use in some circumstances Because of its comparatively high price, NovoSeven is not the front line therapy, which remains, after IT, Feiba VH and to a lesser extent, Autoplex T The latter product has undergone some technical improvements and acceptance seems to be growing , as its share among the high responders gained two percentage points since last year

7) PROPHYLAXIS

Primary prophylaxis is a protocol aimed at the "Previously Untreated Patients or "PUPs" The purpose of a prophylactic regimen is to avoid joint damages caused by repeated bleeding The experience dating back to several decades in Sweden and Germany has shown that prophylaxis can improve the health status of hemophilia patients and enable them to lead a quasi normal lifestyle including sports activities

The protocol involves the infusion of Factor VIII or IX at a dosage of about 25 to 50 IUs per Kilogram bodyweight, depending on the physician's school of thought, three times a week (hemophilia A) or two times a week (hemophilia B) This regimen is the same for inhibitor patients who have been "tolerized", and are on a maintenance regimen following immune tolerance There are variations in the concept of primary prophylaxis, especially as regards the starting date of the protocol, after or before the first joint bleed, and as regards the periodicity of the infusions as well

Secondary prophylaxis consists in a similar regimen as primary prophylaxis, applied to adult or teenage patients for a limited period For a few treaters, it merely consists in infusing clotting factor before engaging into sports or physical activities While the number of patients on prophylaxis went slowly up initially, the pace has increased recently, as shown below

Percentage of Hemophilia Patients on Prophylaxis

	Percentage of Patients in the Sample			
Product	(Jan '00)	(Jan '99)	(Jan '98)	(Jan '98)
Primary Prophylaxis	4 7%	3 9%	3 0%	2 2%
Secondary Prophylaxis	9 6%	7 6%	7 0%	5 0%
Total	14 3%	11 5%	10 0%	7 2%

The survey data show that 14 3% of the hemophilia patients in the sample underwent prophylaxis (650/4,561, an increase of 2 8 percentage points since last year, 11 5%) This was 4 3% more than in 1998 (10 0%) The growing acceptance of prophylaxis is one of the reasons for the overall growth of the market in volume Prophylaxis is increasingly accepted by hemophilia patients because of the perceived higher safety of the clotting factors, the comparatively lower price and easier reimbursement, greater comfort, and enhanced lifestyle in the long run Besides the NHF's Medical and Scientific Advisory Committee (MASAC) recommended several years ago that a newborn with hemophilia be subjected to primary prophylaxis

8) PHS PRICING AND PROFIT MARGINS

As of January 2000, some 45 hemophilia treatment centers had taken advantage of the "VA Bill", and obtained from the manufacturers that the PHS price be applied to them when ordering coagulation factor concentrates The introduction of PHS pricing has eroded the profit margin of the manufacturers of coagulation factor concentrates, even though it was a welcome relief for the patients, – at least those to whom the savings were passed on by the Hemophilia Treatment Center –

Virtually every product has been affected by PHS pricing in the past seven years, as shown below With respect to the Factor VIII products, the decrease ranged from -22 4% (Hemofil M) to a 58% increase for Koate DVI which was an enhanced product from Koate HP As regards the Factor IX products, the decline ranged from nearly -25% (AlphaNine SD) to -0 7% (Profilnine SD)

Changes in the Acquisition and Patient Prices of

Coagulation Factor Concentrates between 1993 and 2000

Product	Acquisition Prices	Patient Prices
Kogenate	-6 5%	-17 [illegible]%
Recombinate	-14 8%	-24 [illegible]%
Hemofil M	-22 4%	-18 [illegible]%
Monarc - M	-12 0%	20 [illegible]%
Monoclate P	-12 4%	1 [illegible]%
Koate DVI/HP	+58 9%	30 [illegible]%
AlphaNine SD	-25 2%	-21 [illegible]%
Mononine	-10 1%	6 [illegible]%
Konyne 80	-0 7%	9 [illegible]%
Feiba VH	-4 9%	14 [illegible]%
Autoplex T	-14 0%	20 [illegible]%
Hyate C	33 5%	42 [illegible]%
Humate P	-27 9%	-42 %

When considering the patient prices, however, a different picture emerged as the prices of some products went down in 1999 after several years of increase, reducing the margin of hospitals and home care companies, after the PHS prices eroded the margins of the manufacturers of clotting factors.

9) HOME CARE

Some 1,690 patients, or 37% of the patients in the sample were enrolled by a home care compan Considering that the total hemophilia population is approximately 17,000 persons (see below, and that the percentage of severe and moderate is 68% (according to the CDC) then the number of candidates for home care is about 11,600 Taking other third party information into accoun then the number of patients served by the major home care companies was estimated as follows

Home Care Company	Estimated Number of Patients
Caremark	2,800
Gentiva	2,500
HHS	1,200
HRA	650
NuFactor	250
AHF	130
Coram	90
Apex	80
ASD Direct	50
HTC's	1,800
Others	2,000
Total	11,550

The erosion of the acquisition prices has been advantageous to the home care companies A simple calculation shows that setting up a home care company can be a very profitable business although it is obviously not for everyone because it requires a high degree of competence dedication and understanding of the hemophilia patients, in addition to high quality services This nevertheless explains why many home care companies were created in recent years, as illustrated at every annual meeting of the National Hemophilia Foundation, where the exhibit floor displayed new home care companies every year However, since the number of hemophilia patients does not change the patient base of each company has eroded as a result of the competition Furthermore a growing number of treatment centers taking advantage of the VA bill created "home care-like" establishments, and enrolled patients who previously were using the services of home care companies

Today, several hemophilia treatment centers offer similar services as the home care companies or claim to do so, in particular such services as drop shipment and 24 hours emergency supp services. For their part, the home care companies offer a more personalized service to the patients

For example, they often sponsor educational activities for patients and parents, they subsidize summer and winter camps and other recreational or educational activities, they publish books and magazines for hemophiliacs, in some cases for specific age groups Most home care companies send patients to the annual meeting of the NHF where a considerable amount of product, scientific and social information can be gathered, in addition to invaluable social contacts Some home care companies make other drugs available to the patients, for instance those needed by HIV positive hemophilia patients Most home care companies employ persons with hemophilia, as they have a first hand understanding and compassion towards the hemophilia patients affiliated with the company Today, the hemophilia patients know more about hemophilia and their treatment than they used to The home care companies assist them in this educational process

Caremark Therapeutic and *Olsten Health Services (now called "Centiva Health Services"), and Hemophilia Health Services (HHS)* are the largest three home care companies, with respectively 28%, 27% and 10% of the patients in the sample The growth of *Hemophilia Resources of America* (HRA) which is primarily present in New Jersey, Ohio, North Carolina and Texas, was also noted New home care organizations, both commercial and not-for-profit were created, often founded by patients' or parents' group ("Biopartners in Care"), or by a distributor of blood products ("NuFactor", founded by FFF Enterprises "Apex Medical", by ActSys Medical, 'ASD Direct', by ASD, a subsidiary of Bergen Brunswick, etc)[1]

Whenever comments were made about the home care companies the respondents emphasized the importance of the representative a company may be highly praised in one region, thanks to a very competent and affable representative, while the same company may be strongly criticized in another region because of the lack of competence or attitude of the local representative

Table 8

HEMOPHILIA CARE AND PRICE MONITORING

IN THE UNITED STATES WAVE #10 - JANUARY 2000

Distribution of Hemophilia Patients among Home Care Companies In the Survey Sample -January 2000

	January '00		January 1999	January 1998	January 1997	April 1996	Septembe 1995
Company	Patients	Percent	Percent	Percent	Percent	Percen	Percen
Caremark	467	28%	37%	43%	34%	32%	36%
Gentiva	452	27%	27%	32%	26%	30%	3[illegible]
HHS	170	10%	13%	8%	8%	[illegible]%	3%
HRA	120	7%	10%	6%	3%	2%	N.A.
HTC	114	7%	N.A.	N.A.	N.A.	N.A.	N.A.
All Others	367	22%	14%	11%	29%	29%	24%
Total	1,690	100%	100%	100%	100%	100%	[illegible]%

10) DEMOGRAPHIC DATA

According to the Centers for Disease Control, the following patients population was estimated in 1994 (latest data available)

Type of Bleeding Disorder	1994
Hemophilia A	13,320
Hemophilia B	3,640

The Centers for Disease Control (CDC) has not updated the above numbers The only new figure available is the number of persons with von Willebrand's Disease which is estimated by the CD at 6,743, in early 2000 The hemophilia population is stable because the number of deaths approximately equals the number of births

11) MARKET PROSPECTS FOR 2000

11 1) Units

In 2000, the demand for rFVIII and rFIX is expected to continue to increase, as more product becomes available, primary and secondary prophylaxis and immune tolerance regimens are prescribed, and pricing is not a major concern

Kogenate FS may be introduced this year in the United States, as it was approved in some European countries More *Recombinate* units will be available, as Baxter's new plant in Thousand Oaks, California increases its production further The supply of *Helixate* and *Bioclate* will follow the trends set by Kogenate and Recombinate The market introduction of *ReFacto* will also ease up the availability of recombinant Factor VIII

With respect to the plasma-derived products, the normalization of the supply of *Monoclate P* has already begun to be felt on the market in early 2000 The patients switching to this product will possibly be drawn from the pool of those using Monarc-M and Hemofil-M No change is expected regarding the supply of Koate DVI, Hemofil-M and Monarc-M, while Alpha Therapeutic's products may not be available for several months

As regards the Factor IX market, the return of *Mononine* to the market is expected to result in the conversion of some hemophilia B patients from *BeneFIX*, slightly affecting the market share of this product

As regards von Willebrand's Disease, the FDA approval of *Humate P* for this indication and its higher supply will facilitate the treatment of a number of patients, perhaps at the expense of those who had switched to Koate DVI, Alphanate remaining relatively unavailable for some time

The market progression of NovoSeven on the inhibitor market may continue although it is expected to be somewhat hampered by the increased acceptance of immune tolerance IT may also affect the sales of *Feiba VH* and *Autoplex T* although the usage of these products may benefit from the continued absence on Konyne 80 and Profilnine SD from the market As for *Hyate C* , will possibly remain stable in terms of market position and sales If the price of NovoSeven increases it may take more patients away from the other AICC products

11.2) Prices

The survey results show that prices began to climb in 1999 This did not influence usage in an significant way, as shown by the continued progression of the recombinant concentrates As long as the U.S economy is healthy, and the insurance companies can fund hemophilia care pricing will continue to remain a secondary issue, unlike several years ago

12) METHODOLOGY

The sample of this survey wave comprised 3,433 hemophilia A and 1 128 hemophilia B patients If one assumes that the average volume of clotting Factor used by the hemophilia patients is comparable from one product to another, then the above market shares reflect the market shares in Factor VIII and Factor IX units as well although BeneFIX' lower recovery would require an adjustment in units used of about 20% upward Using the pricing data, the market shares in value can be estimated

Over 50 hemophilia treatment centers in the continental United States were called in January and February 2000 Approximately thirty to forty were the same as in the previous waves promoting data consistency The others either declined to participate, or had undergone some staff or other changes, and they were replaced by new ones. In many instances, the data were provided by fax and confirmed by telephone, along with qualitative information

While the quantitative and qualitative objectives of this survey are believed to have been met the administration of the survey has faced the same difficulties as last year linked with the higher workload of the treatment centers' staff This situation may result from